IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit	: 3733	**Customer No.: 035811**
Examiner	:	
Serial No.	: 10/589,314	
Filed	: August 11, 2006	
PCT No.	: PCT/FR2005/000340	
PCT Filed	: February 11, 2005	
Inventors	: Maurice Bourlion	Docket No.: BDM-06-1214
	: Dominique Petit	
	: Gérard Vanacker	Confirmation No.: 6499
Title	: DEVICES THAT MONITOR	
	: PENETRATION OF AN	
	: INSTRUMENT IN AN	
	: ANATOMICAL STRUCTURE	
		Dated: October 11, 2007

PETITION UNDER 37 C.F.R. §1.47(a)

Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

This is a petition to accept the attached Combined Declaration, Power of Attorney and Petition unsigned by the third listed inventor of record. Inventor Gérard Vanacker received multiple requests for his signature sent to his representative at Cabinet Versini-Campinchi & Associés, but has not returned the executed document. Joint inventors Maurice Bourlion and Dominique Petit hereby request that the Application be accepted and prosecuted on behalf of Mr. Vanacker.

Statement of Facts

Mr. Vanacker was employed by Spinevision on July 22, 1999 as shown in the Employment Contract in the attached Exhibit A. (An English translation of the Employment Contract is provided.) Mr. Vanacker is no longer employed by Spinevision. Mr. Vanacker was obligated to assign inventions to Spinevision as shown in the Employment Contract (see Article 13).

On October 26, 2006, Proskauer Rose LLP, Spinevision's representative, sent a letter to Mr. Vanacker's consultant Cabinet Versini-Campinchi & Associés with an Oath and an Assignment requesting Mr. Vanacker's signature. Neither Cabinet Versini-Campinchi & Associés nor Mr. Vanacker responded. Copies of the letter, an English translation of the letter, enclosures concerning the second listed invention, and proof of receipt by Cabinet Versini-Campinchi & Associés of the October 26, 2006 letter are attached as Exhibit B.

Proskauer Rose, on November 28, 2006, sent a follow-up letter with another Oath and Assignment to Cabinet Versini-Campinchi & Associés and requested that Mr. Vanacker execute the documents and return them to Proskauer Rose. Again, neither Mr. Vanacker nor Cabinet Versini-Campinchi & Associés replied. Copies of the letter, an English translation of the letter, enclosures concerning item 3 in the letter, and proof of receipt are submitted herewith as Exhibit C.

Lovells LLP, on September 19, 2007, sent a follow-up letter with another Oath and Assignment to Mr. Vanacker requesting that he execute the documents and return them to Lovells LLP. Again, Mr. Vanacker did not reply. Copies of the letter, an English translation of the letter and the enclosures referred to in the letter are submitted herewith as Exhibit D.

It is therefore believed that Mr. Vanacker has refused to sign the Declaration.

Last Known Contact Information of Non-signing Inventor

The last known address of Mr. Vanacker is:

Villa Saint Antoine
2 rue du Sautiquet
83380 Les Issambres

The last known address of Mr. Vanacker's representative is:

Cabinet Versini-Campinchi & Associés
MonsieurAlexandre Merveille
Avocat à la Cour
4, rue de la Tour des Dames
75009 Paris, France

The Combined Declaration, Power of Attorney and Petition executed by the other inventors is attached hereto.

The Commissioner is authorized to charge the late declaration fee ($130) and the petition fee ($200) to Deposit Account No. 50-2719.

Confirmation of the granting of this Petition is respectfully requested.

Respectfully submitted,

T. Daniel Christenbury
Reg. No. 31,750
Attorney for Applicants

TDC/sh
(215) 656-3381

EXHIBIT A

Employment Contract

BETWEEN:

SPINEVISION, a public company with 38,325 euros in capital, having corporate headquarters located on 22 rue Alphonse De Neuville, 75017 Paris, registered with the Registry of Commerce and Companies of Paris under the number 423 661 693 (hereafter "the Company"), and represented by Mrs. Sarah Sorrel-Dejerine in her capacity as President of the Board of Directors;

ON THE ONE HAND,

And

Mr. **Gérard VANACKER**, a French citizen, domiciled at 52, avenue François Adam, 94100 ST MAUR;

ON THE OTHER HAND.

THE PARTIES AGREE TO THE FOLLOWING:

The Company has offered Gérard Vanacker, who has accepted, a position of employment under the following specific terms and conditions, as well as under conditions provided for by the National Collective Bargaining Agreement of Engineers and Metallurgy Executives (hereafter "Collective Bargaining Agreement"), and which is contingent on the results from the pre-employment medical examination.

Article 1 – Functions – Promotions

Gérard Vanacker begins service with the Company as the Director of Sales and Marketing, executive status, grade 240. Within the context of this position, Gérard Vanacker will be responsible for following the instructions that the Company will be giving him and will be responsible for reporting to the President of the Company as to the execution of his mission.

It is understood, and accepted by Gérard Vanacker that his position will be able to evolve and that the Company will be amenable to modifying and completing his functions and responsibilities.

Article 2 – Place of Work

The place of work is fixed at the headquarters of the Company and/or on the operational premises of the Company located in the Paris region, it being understood that the functions of Gérard Vanacker will result in frequent travel, within France and abroad.

Article 3 – Freedom of Engagement

Gérard Vanacker declares that he is not held to any other agreement with or obligation to any previous employers which would prevent him from working for the Company.

Gérard Vanacker declares that, during the entire duration of his employment with the Company, he will neither use nor divulge any confidential or secret processes information belonging to any of his previous employers.

Article 4 – Duration

The present contract is entered into for an indeterminate duration beginning from July 22, 1999.

Article 5 – Obligations and Duties

5.1 Gérard Vanacker is being hired to exercise his functions loyally and to the best of his abilities. He will not, except if he has received prior written authorization from the Company, be involved in any other professional activity of any type, nor will he involve himself in any manner with any activity that would be in competition with the Company or that is in conflict with the interests of the activities of the Company.

5.2 Within the context of his employment functions, Gérard Vanacker will be entitled to conclude any agreement which may undertake the Company in conformity with the policies and the directives passed by the board of directors of the Company.

5.3 All publications or communications of Gérard Vanacker concerning the activities or the interests of the Company will be preliminarily authorized by the President of the board of directors, except publications or communications concerning the promotion of sales of the Company or the daily functions of Gérard Vanacker.

Article 6 – Compensation

6.1 The Company will pay Gérard Vanacker a base annual gross salary of six hundred thousand (600,000) francs, payable in twelve monthly installments at the end of each month.

6.2 The Company will proceed annually with an evaluation of Gérard Vanacker's performance and will contemplate a procedure to increase his salary such that it is tied to his performance, at each anniversary date of the present contract. Despite all clauses contrary to the present contract, it is expressly agreed that all bonuses, incentives, commissions, gifts, or any other payment included in the compensation set forth in this Article 6 will not be considered an element of salary that Gérard Vanacker will have a contractual right to receive, but rather as generosity that the Company reserves the right to cease or revise at any moment and at its sole discretion.

(Please note that the original French version does not mention any article 6.3)

6.4 It has been agreed that the compensation of Gérard Vanacker will be based upon a 39-hour work week. However, it is understood that the said compensation will take into account the nature of the functions and responsibilities which have been entrusted to him and will remain independent of the time that he dedicates to accomplishing them, in the exercise of his functions.

Article 7 – Vacation Pay

Gérard Vanacker will benefit from vacation time set forth by law and the Collective Bargaining Agreement, of which the scheduling will be determined by agreement between the Company and Vanacker, taking into account the demands of his service.

Article 8 – Incapacity

In the event of incapacity to work following an illness or accident, Gérard Vanacker must inform the management from the beginning of the first workday of his incapacity by submitting a medical certificate to the personnel department of the Company. The Company reserves the right to submit Gérard Vanacker to an examination by a doctor of its choice.

Article 9 – Expenses

Within the context of the regulations/policies in place within the Company, Gérard Vanacker will be reimbursed, upon presentation of his justifications for incurring such expenses, for all his professional expenses, including his travel costs incurred within the context of his functions within the Company.

Article 10 – Secret – Confidentiality

10.1 Gérard Vanacker recognizes that the activities of the Company are based on specialized work and a specific know-how, and that confidential information will be communicated to him within the context of this present contract. The term "confidential information" means all information that is not known publicly, concerning the activities of the Company, including, without limitation, all plans, production procedures, product and formula specifications, methods, technical bulletins and product bulletins, all data regarding the equipment sold or data regarding performance of services, as well as studies, research and development programs, correspondences, client lists, names of clients or prospects, sales reports and financial information.

10.2 Gérard Vanacker agrees, for both during the time he is exercising his functions within the Company as well as after those responsibilities/functions end for whatever reason, to maintain in the strictest of confidences the Confidential Information and to neither use the information nor communicate it to any their parties, whether a human being or a corporation, without the preliminary, written consent of the Company.

Article 11 – Non-Compete

Gérard Vanacker is prohibited, during a period of one (1) year (renewable one time) from the end of his employment contract with the Company, for whatever the reason:

(a) from leading directly or indirectly, alone or in concert, as head or agent of another corporation or person, any competitive activity against the Company, without the prior written consent of the Company. By using the term "lead", it includes all activity in which he would be engaged, have an interest or more generally be in involved. The term "competing activity" refers to all activity in the domain of implants and spinal instruments.

(b) In consideration for Gérard Vanacker's agreement not to compete, and pursuant to the provisions of the Collective Bargaining Agreement, Gérard Vanacker will receive, after the effective termination of his employment contract and during the entire duration of the non-compete prohibition, a monthly indemnity equal to five-tenths of the average monthly salary and advantages and contractual benefits of which Gérard Vanacker had benefited during the course of his last twelve months of employment with the Company.

(c) The Company may however renounce its right to enforce the non-compete in any way—and, likewise, renounce its obligation of payment of the indemnity in consideration of that non-compete obligation—provided that it notifies Gérard Vanacker of its decision by letter with return receipt requested within 8 days following the notification of termination of the employment contract.

(d) In the event of the breach of this non-compete clause by Gérard Vanacker, the Company reserves the right to pursue damages for any prejudice actually suffered by the Company and to move to enjoin any competitive activity.

Article 12 – Non-Solicitation – No poaching

Notwithstanding all other stipulations in the present contract, Gérard Vanacker also agrees that during the two years immediately following the termination of the present contract he will not:

(a) sell any products or services door-to-door that could be potentially competitive with the products of the Company, the clientele of the Company or its affiliates;

(b) do business with the products or services of any person or corporation which would have been the client of the Company or of its affiliates during the two (2) years prior to the departure of Gérard Vanacker from the Company;

(c) employ people who were employees of the Company in the year preceding the termination of the present contract, nor hire them through any other people, establishments, companies by which he [Gérard Vanacker] could be employed, or in which he has a direct or indirect interest, and agrees that he will not use his influence

over any person employed by the Company to suggest to that person or persuade him to leave his current post.

Article 13 – Intellectual Property and/or Trade Secret Rights

If, pursuant to the provisions of the Collective Bargaining Agreement, in the exercise of his functions, which include a creative mission—which has been taking into consideration in determining his compensation—Gérard Vanacker created an invention, patentable or not, created any drawings, models, methods, programs, formulas or processes in relation with the company's activities, projects or research of the Company and susceptible to being protected, the intellectual property or trade secret rights to that creation belongs to the Company in full.

However, if an invention created by Gérard Vanacker in the context of his functions provided the Company with an exceptional interest which was not commensurately compensated for in the inventor's salary, then after the issuance of the patent, a supplemental compensation that could take the form of a global bonus paid in once or several installments will be paid to the inventor.

However, if Gérard Vanacker conceived of an invention or a creation covered above without the support, help or aid of the Company, and did not use any activities, nor studies, nor research of the company, the rights of the resulting intellectual property or trade secret belong to Gérard Vanacker.

Article 14 – Termination

In the event of the termination or suspension of the present contract for any reason (resignation, termination, retirement, medical leave spanning over three calendar months, etc.), Gérard Vanacker will return to the Company, at the time of his departure from the Company and whatever the duration of the present contract, all documents, notes, reports, accounting reports, drawings, lists, credit cards and correspondences, including all copies, as well as all material, computer or electronic support, equipment and the Company car, which remain at all times the property of the Company.

Article 15 – Applicable Law

The present contract is governed by the laws of France.

In double copies, July 22, 1999, executed in Paris

SpineVision represented by
Mrs. Sarah Sorrel-Dejerine
In her capacity as President of the Board of Directors

Gérard VANACKER

*The signatures must be preceded by the phrase "read and approved"; each page must be initialed by both parties.

CONTRAT DE TRAVAIL

ENTRE LES SOUSSIGNES:

SPINEVISION, société anonyme au capital de 38.325 Euros, dont le siège social est situé 22 rue Alphonse De Neuville, 75017 Paris, immatriculée auprès du Registre du Commerce et des Sociétés de Paris sous le numéro 423 661 693 (ci-après la "Société"), représentée par Madame Sarah Sorrel-Dejerine en sa qualité de Président du Conseil d'administration ;

D'UNE PART,

ET

Monsieur **Gérard VANACKER**, de nationalité française, demeurant au 52, avenue François Adam, 94100 ST MAUR ;

D'AUTRE PART,

IL A ETE CONVENU ET ARRETE CE QUI SUIT :

La Société engage Gérard Vanacker, qui accepte, aux termes et aux conditions particulières suivants ainsi qu'aux conditions prévues par la Convention Collective Nationale des ingénieurs et cadres de la métallurgie (ci-après "la Convention Collective"), sous réserve du résultat de la visite médicale d'embauche.

Article 1 - Fonctions - Clause de mobilité

Gérard Vanacker entre au service de la Société en qualité de Directeur des Ventes et du Marketing, statut cadre, coefficient 240. Dans le cadre de ses fonctions, Gérard Vanacker sera chargé de suivre les instructions que la Société pourra lui donner et rendre périodiquement compte au Président de la Société de l'exécution de sa mission.

Il est entendu, et accepté par Gérard Vanacker, que le poste de Gérard Vanacker pourra évoluer et que la Société pourra être amenée à modifier et compléter ses fonctions et responsabilités.

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Article 2- Lieu du travail

Le lieu du travail est fixé au siège social de la Société et/ou dans les locaux opérationnels de la Société situés dans la région parisienne, étant convenu que les fonctions de Gérard Vanacker le conduiront à se déplacer fréquemment, en France et à l'étranger.

Article 3 - Liberté d'engagement

Gérard Vanacker déclare qu'il n'est tenu par aucun engagement à l'égard de précédents employeurs, qui l'empêcherait de rejoindre la Société.

Gérard Vanacker déclare que, pendant toute la durée de son emploi au sein de la Société, il n'utilisera ni ne divulguera aucune information confidentielle ou secret de fabrique appartenant à l'un quelconque de ses précédents employeurs.

Article 4 - Durée

Le présent contrat est conclu pour une durée indéterminée à compter du 22 juillet 1999.

Article 5 - Obligations de fidélité

5.1 Gérard Vanacker s'engage à exercer ses fonctions loyalement et au mieux de ses aptitudes. Il ne pourra, sauf s'il en reçoit l'autorisation écrite et préalable de la Société, avoir aucune autre activité professionnelle quelle qu'elle soit, ni s'intéresser de quelque manière que ce soit à aucune activité entrant en concurrence ou en conflit d'intérêts avec les activités de la Société.

5.2 Dans le cadre de ses fonctions salariés, Gérard Vanacker pourra conclure tout accord engageant la Société en conformité avec la politique et les directives arrêtées par le conseil d'administration de la Société.

5.3 Toute publication ou communication de Gérard Vanacker concernant les activités ou les intérêts de la Société devront être préalablement autorisés par le Président du Conseil d'administration, sauf publication ou communication concernant la promotion des ventes de la Société ou les fonctions habituelles de Gérard Vanacker.

Article 6- Rémunération

6.1 La Société versera à Gérard Vanacker un salaire de base annuel brut de six cent mille (600.000) francs, payable en douze mensualités à terme échu.

6.2 La Société procédera annuellement à une évaluation des résultats de Gérard Vanacker et pourra envisager de procéder à des augmentations de salaire liées auxdits résultats, à chaque date anniversaire du présent contrat. Nonobstant toute disposition contraire du présent contrat, il est expressément convenu que tout bonus, prime, commission, libéralité ou autre paiement s'ajoutant aux rémunérations du présent Article 6 ne sera pas considéré comme un élément de salaire que Gérard Vanacker serait contractuellement en droit de recevoir, mais comme une libéralité que la Société se réserve le droit de cesser ou réviser à tout moment et à sa seule discrétion.

6.4 La rémunération de Gérard Vanacker a été convenue sur la base d'un horaire hebdomadaire de 39 heures. Toutefois, il est entendu que ladite rémunération tient compte de la nature des fonctions et responsabilités qui lui sont confiées et restera indépendante du temps qu'il consacrera de fait, à l'exercice de ses fonctions.

Article 7- Congés payés

Gérard Vanacker bénéficiera des congés prévus par la loi et la Convention Collective, dont l'époque sera déterminée par accord entre la Société et Gérard Vanacker, compte tenu des nécessités du service.

Article 8 - Maladie

En cas d'incapacité de travail par suite de maladie ou d'accident, Gérard Vanacker doit avertir la Direction dès le début du premier jour ouvrable de son incapacité en remettant un certificat médical au service du personnel de la Société. La Société se réserve le droit de faire procéder à une contre-visite par un médecin de son choix.

Article 9 - Frais

Dans le respect des règles en vigueur au sein de la Société, Gérard Vanacker sera remboursé, sur présentation de justificatifs, de toutes ses dépenses professionnelles, y compris les frais de déplacement exposés dans le cadre de ses fonctions au sein de la Société.

Article 10- Secret - Confidentialité

10.1 Gérard Vanacker reconnaît que les activités de la Société sont basées sur un travail spécialisé et un savoir-faire spécifique, et que des informations confidentielles lui seront communiquées dans le cadre du présent contrat. Le terme «Informations Confidentielles» signifie toutes informations qui ne sont pas connues du public, concernant les activités de la Société, y compris, sans limitation, tous plans, procédés de production, spécifications de produits et formules, méthodes, bulletins techniques et bulletins produits, toutes données concernant les équipements vendus ou faisant l'objet de prestations de service, ainsi que les études, programmes de recherche et développement, correspondances, listes de clients, noms des clients ou prospectus, rapports de vente et informations financières.

SKD
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10.2 Gérard Vanacker s'engage, tant pendant la durée de ses fonctions au sein de la Société qu'après leur cessation pour quelque raison que ce soit, à conserver la confidentialité la plus stricte sur les Informations Confidentielles et à ne pas les utiliser, ni les communiquer à un tiers, personne physique ou morale, sans l'accord préalable et écrit de la Société.

Article 11 - Non-concurrence

Gérard Vanacker s'interdit, pendant une période d'un (1) an (renouvelable une fois) à compter de la cessation de son contrat de travail au sein de la Société, pour quelque motif que ce soit:

(a) à ne pas mener directement ou indirectement, seul ou de concert, comme dirigeant ou préposé de toute autre personne morale ou physique, une activité concurrente à celle de la Société, sans le consentement écrit et préalable de la Société. Par l'utilisation du terme "mener", on entend toute activité dans laquelle il serait engagé, intéressé ou plus généralement impliqué. Par "activité concurrente", il faut entendre, toute activité dans le domaine des implants et des instruments rachidiens.

(b) En contrepartie de l'obligation de non-concurrence ci-dessus et conformément aux dispositions de la Convention Collective, Monsieur Gérard Vanacker percevra, après la cessation effective de son contrat de travail et pendant toute la durée de cette interdiction, une indemnité mensuelle égale à cinq dixièmes de la moyenne mensuelle des appointements et des avantages et gratifications contractuels dont Gérard Vanacker a bénéficié au cours de ses douze derniers mois de présence dans la Société.

(c) La Société pourra cependant renoncer au bénéfice de l'obligation de non concurrence visée plus haut - et par là-même se dégager du paiement de l'indemnité prévue en contrepartie - sous réserve de notifier cette décision à Monsieur Gérard Vanacker par lettre recommandée avec accusé de réception dans les huit jours qui suivent la notification de la rupture du contrat de travail.

(d) En cas de non-respect de la présente clause de non-concurrence par Monsieur Gérard Vanacker, la Société se réserve le droit de le poursuivre en remboursement du préjudice effectivement subi et de faire ordonner sous astreinte la cessation de l'activité concurrentielle.

Article 12 - Non-sollicitation - Non-débauchage

Nonobstant toute autre stipulation du présent contrat, Monsieur Gérard Vanacker s'engage par ailleurs pendant une durée de deux ans à compter de la résiliation du présent contrat :

(a) à ne pas démarcher, pour tout produit ou service susceptible de faire concurrence aux produits de la Société, la clientèle de la Société ou de ses sociétés affiliées ;

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(b) à ne pas traiter pour ces produits ou services avec toute personne physique ou morale qui aura été le client de la Société ou de ses sociétés affiliées à quelque moment que ce soit pendant les deux (2) années précédant le départ effectif de Gérard Vanacker de la Société ;

(c) à ne pas employer les personnes qui étaient employées par la Société dans l'année précédant la résiliation du présent contrat, ni les faire employer par toutes autres personnes, établissements, sociétés par lesquels il pourrait être employé, ou auxquels il pourrait être directement ou indirectement intéressé, et à ne pas utiliser son influence sur toute personne employée par la Société dans le but de lui suggérer ou de la persuader de quitter son poste.

Article 13 - Droits de propriété intellectuelle et/ou industrielle

Si, conformément aux dispositions de la Convention Collective, dans l'exercice de ses fonctions, qui comportent une mission inventive -ce dont il a été tenu compte dans la détermination de sa rémunération- Gérard Vanacker réalisait une invention, brevetable ou non, créait des dessins, modèles, méthodes, programmes, formules ou procédés ayant trait aux activités, projets ou recherches de la Société et susceptibles d'être protégés, les droits de propriété intellectuelle ou industrielle appartiendraient à la Société de plein droit.

Toutefois, si une invention dont Gérard Vanacker serait l'auteur dans le cadre de ses fonctions présentait pour la Société un intérêt exceptionnel dont l'importance serait sans commune mesure avec le salaire de l'inventeur, celui-ci se verrait attribuer après la délivrance du brevet, une rémunération supplémentaire pouvant prendre la forme d'une prime globale versée en une ou plusieurs fois.

Toutefois, Si Gérard Vanacker réalisait une invention ou une création visée ci-dessus sans le concours de la Société, et n'ayant trait ni aux activités, ni aux études ou recherches de la Société, les droits de propriété intellectuelle ou industrielle en résultant appartiendraient à Gérard Vanacker.

Article 14 - Résiliation

En cas de résiliation ou de suspension du présent contrat pour quelque raison que ce soit (démission, licenciement, départ en retraite, congé-maladie supérieur à trois mois civils, etc.), Gérard Vanacker remettra à la Société, lors de son départ de la Société et quelle que soit la durée du présent contrat, tous documents, notes, rapports, comptes-rendus, dessins, listes, cartes de crédit et correspondances, y compris toutes copies, ainsi que tout matériel, supports informatiques ou électroniques, équipement et véhicule de fonctions, qui demeureront à tout moment la propriété de la Société.

SD
VF

Article 15 - Loi applicable

Le présent contrat est soumis au droit français.

En double exemplaire, le 22 juillet 1999, à Paris

	lu et approuvé
	*
SpineVision représentée par	Gérard VANACKER
Madame Sarah Sorrel-Dejerine	
en sa qualité de Président du Conseil d'administration ;	

* *Les signatures doivent être précédées de la mention manuscrite «Lu et approuvé» ; chaque page doit être paraphée par les deux parties.*

EXHIBIT B

Paris, October 26, 2006

Cabinet Versini-Campinchi & Associés
Monsieur Alexandre Merveille
Avocat à la Cour
4, rue de la Tour des Dames
75009 Paris

By Courier

Official Letter

Re: Spinevision / Vanacker

Dear Colleague:

Enclosed are the documents (powers of attorney and transfer deed) which must be signed, notably, by your client, Mr. Gérard Vanacker, so that the following patents may be registered with the requisite authorities in the United States:

- Exploration device for monitoring the penetration of an instrument into an anatomical structure;
- Device for following the penetration of an instrument in an anatomical structure;
- Device for monitoring the penetration of an instrument into an anatomical structure;

Please return them to us as soon as possible.

In the event that your client does not agree to execute these documents, please notify us as soon as possible.

Please do not hesitate to let us know if you need any additional information.

Sincerely,

Yasmine Tarasewicz / Béatrice Pola
Attorneys At Law

PJ.

C.C.: Société Spinevision

PROSKAUER ROSE
Avocats au Barreau de Paris

374, rue Saint-Honoré
75001 Paris, France
Téléphone 33.1.53.05.60.00
Fax 33.1.53.05.60.05
Palais J043

NEW YORK
LOS ANGELES
WASHINGTON
BOCA RATON
BOSTON
NEWARK

Paris, le 26 octobre 2006

Cabinet Versini-Campinchi & Associés
Monsieur Alexandre Merveille
Avocat à la Cour
4, rue de la Tour des Dames
75009 Paris

Par porteur

Lettre officielle

Objet : Spinevison / Vanacker

Cher Confrère,

Vous trouverez ci-après les documents (pouvoirs et cessions) qui doivent êtres signés, notamment, par votre client, Monsieur Gérard Vanacker, afin que les brevets :

- Exploration device for monitoring the penetration of an instrument into an anatomical structure ;
- Device for following the penetration of an instrument in an anatomical structure ;
- Device for monitoring the penetration of an instrument into an anatomical structure ;

soient déposés devant les autorités requises aux Etats-Unis.

Nous vous remercions de bien vouloir nous retourner rapidement ces derniers.

Dans l'hypothèse où votre client n'entendrait pas procéder à ces signatures, nous vous remercions de bien vouloir nous le préciser en retour.

Nous restons bien entendu à votre entière disposition pour tout renseignement complémentaire que vous pourriez souhaiter.

Nous vous prions de nous croire, Cher Confrère,

Vos bien dévouées.

Yasmine Tarasewicz / Béatrice Pola
Avocats à la Cour

PJ.

C.C. : Société Spinevision

Attorney Docket No. BDM-06-1214

☐ Original Application
☒ PCT National Application
U.S. Designated Office
☐ Continuation or Divisional Application
☐ Continuation-in-Part Application

COMBINED DECLARATION,
POWER OF ATTORNEY AND PETITION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE

☐ which is described in the specification and claims

☐ attached hereto.

☐ filed on _____

Application Serial No. _____

and was amended on _____
(*if applicable*)

☒ which is described in International Application No. PCT/FR2005/000340

filed February 11, 2005 and as amended on

_____ (if any),

which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION
(Page 2)

Attorney Docket No. BDM-06-1214

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International Application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT International Application having a filing date before that of the application on which priority is claimed:

Number	Country	Date of Filing (day,month,year)	Priority Claimed
0401362	France	11 February 2004	☒ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no

I hereby claim the benefit under Title 35, United States Code, §119(e) or §120 (as applicable) of any United States application(s) or §365(c) of any PCT International Application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International Application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112:

(Application Serial No.)	*(Filing Date)*	*(Status)(patented,pending,abandoned)*
(Application Serial No.)	*(Filing Date)*	*(Status)(patented,pending,abandoned)*

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered attorneys to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

T. Daniel Christenbury	Reg. No. 31,750	Steven A. Nash	Reg. No. 45,507
Paul A. Taufer	Reg. No. 35,703	Andrew A. Noble	Reg. No. 48,651
Thomas J. Durling	Reg. No. 31,349	Thomas R. Mancini	Reg. No. 50,157
Darius C. Gambino	Reg. No. 41,472	Richard L. Cruz	Reg. No. 52,783
William F. Lang	Reg. No. 41,928	William L. Bartow	Reg. No. 54,981
Paul Carango	Reg. No. 42,386		

SEND CORRESPONDENCE TO: **Customer No. 035811**, whose contact information is: IP Group of DLA Piper Rudnick Gray Cary US LLP One Liberty Place, Suite 4900 1650 Market Street Philadelphia, PA 19103	DIRECT TELEPHONE CALLS TO ATTORNEY OF RECORD AT: (215) 656-3300

COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION
(Page 3)

Attorney Docket No. BDM-06-1214

I hereby petition for grant of a United States Letters Patent on this invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1. FULL NAME OF SOLE OR FIRST INVENTOR	INVENTOR'S SIGNATURE	DATE
Maurice Bourlion		
RESIDENCE	CITIZENSHIP	
Saint-Chamond, France	France	
POST OFFICE ADDRESS		
9 rue Jean Vincent, F-42400 Saint-Chamond, France		
2. FULL NAME OF JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
Gerard Vanacker		
RESIDENCE	CITIZENSHIP	
Tiburon, California, U.S.A	France	
POST OFFICE ADDRESS		
4131 Paradise Drive, US- 94920 Tiburon, California, U.S.A.		
3. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
Dominique Petit		
RESIDENCE	CITIZENSHIP	
Verton, France	France	
POST OFFICE ADDRESS		
2 rue des Peupliers, F-62180 Verton, France		
4. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
5. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
6. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
7. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

BDM-06-1214

ASSIGNMENT

WHEREAS, we, Maurice Bourlion, Gerard Vanacker and Dominique Petit, citizens of France, residing at 9 rue Jean Vincent, F-42400 Saint-Chamond, France; 4131 Paradise Drive, US-94920 Tiburon, California, U.S.A. and 2 rue des Peupliers, F-62180 Verton, France, respectively, (hereinafter referred to as "the undersigned"), having made an invention entitled DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE for which on the date set forth below, unless otherwise indicated here, _____, the undersigned executed an application for United States Letters Patent,

WHEREAS, Spinevision. a corporation of France, with offices at 180 avenue Daumesnil, F-75012 Paris, France (hereinafter referred to as "assignee"), is desirous of acquiring the entire right, title and interest in said invention, said application and all letters patent issuing for said invention,

NOW, THEREFORE, in consideration of One Dollar ($1.00) and of other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the assignee the entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said patent application, all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all letters patent and reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that the undersigned shall be legally bound, upon request of the assignee, or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments proper to patent the invention in the United States of America and foreign countries in the name of the assignee, and to execute all instruments proper to carry out the intent of this instrument. If the undersigned includes more than one individual, these obligations shall apply to all of the undersigned both individually and collectively.

The rights and property herein conveyed by the undersigned are free and clear of any encumbrance.

EXECUTED on _____, 20__, at _____.

_____
Maurice Bourlion

_____
Gerard Vanacker

_____
Dominique Petit

_____
Witness

66.800.001 | N° 128299

Date : 26/10/06 | Coursier : | ☐ Normal | ☐ Urgent | ☒ Exclu

EXPEDITEUR

NOM / SOCIETE : PROSKAUER ROSE LLP

ADRESSE : 374 rue Saint-Honoré
75001 Paris, France
Tél. : 01 53 05 60 00 - Fax : 01 53 05 60 05

Ville et code postal : Siret n° : 407 913 847 00031

Demandeur :

CACHET OBLIGATOIRE :

PROSKAUER ROSE LLP
374 rue Saint-Honoré
75001 Paris, France
Tél. : 01 53 05 60 00 - Fax : 01 53 05 60 05
Siret n° : 407 913 847 00031

Signature :

DESTINATAIRE

NOM / SOCIETE : Gabriel Vachia
Campinchi & Associés

ADRESSE : 4 rue de la Tour des dames

Ville et code postal : 75009 Paris

Réceptionnaire : Mr Marseille Alexandre

CACHET OBLIGATOIRE :

CAMPINCHI & Associés
Société d'Avocats au barreau de Paris
4, rue de la Tour des Dames
75009 PARIS
Tél. 01 45 26 62 41 - Fax 01 48 78 25 22
Vestiaire d'Abs

Heure de livraison :

Signature :

Facturer à :

Observations : Philia (B. Pdo)

Nombre de bons : 6

EXHIBIT C

Paris, November 28, 2006

Cabinet Versini-Campinchi & Associés
Monsieur Alexandre Merveille
Avocat à la Cour
4, rue de la Tour des Dames
75009 Paris

Registered Letter

Official Letter

Re: Spinevision / Vanacker

Dear Colleague:

We have sent you a letter on October 26, 2006, to which we have received no response.

We now ask that you convey to your client, Mr. Gérard Vanacker, the three powers of attorneys and the three transfer deeds pertaining to the three patents, all of which are documents he must sign.

Hereinafter is a new copy of the elements, as well as the complementary documents for each of the patents (a copy of the texts filed at the U.S. Patent Office at the national level for a request for a PCT (Patent Cooperation Traite) patent. Thus,

1. With regard to the patent for "Exploration device for monitoring the penetration of an instrument into an anatomical structure," the copies of the following are enclosed:
   a. The power of attorney
   b. The transfer deed
   c. The French text for the international request for a PCT patent N°PCT/FR2005/000338;
   d. The English text of the U.S. phase of the request for a PCT patent N°PCT/FR2005/000338;
   e. The modified text of the request for a PCT patent pursuant to the requirements of the U.S. Patent Office (Clean Copy).

2. With regard to the patent for "Device for following the penetration of an instrument in an anatomical structure," copies of the following are enclosed:
   a. The power of attorney
   b. The transfer deed
   c. The French text for the international request for a PCT patent N°PCT/FR2005/000873;
   d. The English text of the U.S. phase of the request for a PCT patent N°PCT/FR2005/000873;

e. The modified text of the request for a PCT patent pursuant to the requirements of the U.S. Patent Office (Clean Copy).

3. With regard to the patent for "Device for monitoring the penetration of an instrument into an anatomical structure," copies of the following are enclosed:
   a. The power of attorney
   b. The transfer deed
   c. The French text for the international request for a PCT patent N°PCT/FR2005/000340;
   d. The English text of the U.S. phase of the request for a PCT patent N°PCT/FR2005/000340;
   e. The modified text of the request for a PCT patent pursuant to the requirements of the U.S. Patent Office (Clean Copy).

Please inform us within a week as to the intentions of your client.

In the absence of a response, we will conclude that your client does not intend to associate himself with the three entry national phases in the United States for the PCT patents filed under the following numbers PCT/FR2005/000340, PCT/FR2005/000338 and PCT/FR2005/000873 before the U.S. Patent Office.

Sincerely,

Béatrice Pola
Attorney At Law

PJ.

C.C.: Société Spinevision

RA 3761 9436 1FR

PROSKAUER ROSE
Avocats au Barreau de Paris

374, rue Saint-Honoré
75001 Paris, France
Téléphone 33.1.53.05.60.00
Fax 33.1.53.05.60.05
Palais J043

NEW YORK
LOS ANGELES
WASHINGTON
BOCA RATON
BOSTON
NEWARK

Paris, le 28 novembre 2006

Cabinet Versini-Campinchi & Associés
Monsieur Alexandre Merveille
Avocat à la Cour
4, rue de la Tour des Dames
75009 Paris

LETTRE RECOMMANDEE AR

Lettre officielle

Objet : Spinevison / Vanacker

Cher Confrère,

Nous vous avions adressé le 26 octobre courant une correspondance qui, à ce jour, est restée sans réponse.

Dans cette dernière, nous vous demandions de bien vouloir transmettre à votre client, Monsieur Gérard Vanacker les trois pouvoirs et les trois cessions relatifs à trois brevets, documents qu'il devait signer.

Vous trouverez ci-après une nouvelle copie de ces éléments ainsi que pour chacun des brevets des documents complémentaires (copie des textes déposés à l'office américain des brevets pour la phase nationale de la demande de brevet PCT (Patent Cooperation Traite)). Ainsi,

1. S'agissant du brevet : *"Exploration device for monitoring the penetration of an instrument into anatomical structure"*, vous trouverez ci-après copies :

   - du pouvoir,
   - de l'acte de cession,
   - du texte français de la demande internationale de brevet PCT N°PCT/FR2005/000338 ;
   - du texte anglais de la phase nationale américaine de la demande de brevet PCT N°PCT/FR2005/000338 ;
   - du texte modifié de la demande de brevet PCT qui répond aux exigences de l'office américain de dépôt des brevets (Clean Copy).

2. S'agissant du brevet : *"Device for following the penetration of an instrument in an anatomical structure"* vous trouverez ci-après copies :
   - du pouvoir,
   - de l'acte de cession,
   - du texte français de la demande internationale de brevet PCT N°PCT/FR2005/000873 ;
   - du texte anglais de la phase nationale américaine de la demande de brevet PCT N°PCT/FR2005/000873 ;
   - du texte modifié de la demande de brevet PCT qui répond aux exigences de l'office américain de dépôt des brevets (Clean Copy).

3. S'agissant du brevet : *"Device for monitoring the penetration of an instrument into an anatomical structure"* vous trouverez ci-après copies :
   - du pouvoir,
   - de l'acte de cession,
   - texte français de la demande internationale de brevet PCT N°PCT/FR2005/000340 ;
   - texte anglais de la phase nationale américaine de la demande de brevet PCT N°PCT/FR2005/000340 ;
   - texte modifié de la demande de brevet PCT qui répond aux exigences de l'office américain de dépôt des brevets (Clean Copy).

Je vous remercie de bien vouloir nous fixer sous huitaine sur les intentions de votre client.

A défaut de réponse, j'en conclurai que votre client n'entend pas s'associer aux trois entrées en phase nationale aux Etats-Unis des demandes de brevets PCT déposées sous les numéros PCT/FR2005/000340, PCT/FR2005/000338 et PCT/FR2005/000873 auprès de l'office américain des brevets.

Je vous prie de me croire, Cher Confrère,

Votre bien dévouée.

Béatrice Pola
Avocat à la Cour

PJ.

C.C. : Société Spinevision

Attorney Docket No. BDM-06-1214

☐ Original Application
☒ PCT National Application
U.S. Designated Office
☐ Continuation or Divisional Application
☐ Continuation-in-Part Application

COMBINED DECLARATION,
POWER OF ATTORNEY AND PETITION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE

☐ which is described in the specification and claims

☐ attached hereto.

☐ filed on _____

Application Serial No. _____

and was amended on _____
(*if applicable*)

☒ which is described in International Application No. PCT/FR2005/000340

filed February 11, 2005 and as amended on

_____ (if any),

which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION
(Page 2)

Attorney Docket No. BDM-06-1214

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International Application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT International Application having a filing date before that of the application on which priority is claimed:

Number	Country	Date of Filing (day,month,year)	Priority Claimed
0401362	France	11 February 2004	☒ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no

I hereby claim the benefit under Title 35, United States Code, §119(e) or §120 (as applicable) of any United States application(s) or §365(c) of any PCT International Application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International Application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112:

(Application Serial No.) *(Filing Date)* *(Status)(patented,pending,abandoned)*

(Application Serial No.) *(Filing Date)* *(Status)(patented,pending,abandoned)*

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered attorneys to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

T. Daniel Christenbury	Reg. No. 31,750	Steven A. Nash	Reg. No. 45,507
Paul A. Taufer	Reg. No. 35,703	Andrew A. Noble	Reg. No. 48,651
Thomas J. Durling	Reg. No. 31,349	Thomas R. Mancini	Reg. No. 50,157
Darins C. Gambino	Reg. No. 41,472	Richard L. Cruz	Reg. No. 52,783
William F. Lang	Reg. No. 41,928	William L. Bartow	Reg. No. 54,981
Paul Carango	Reg. No. 42,386		

SEND CORRESPONDENCE TO: **Customer No. 035811, whose contact information is:** IP Group of DLA Piper Rudnick Gray Cary US LLP One Liberty Place, Suite 4900 1650 Market Street Philadelphia, PA 19103	DIRECT TELEPHONE CALLS TO ATTORNEY OF RECORD AT: (215) 656-3300

COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION
(Page 3)

Attorney Docket No. BDM-06-1214

I hereby petition for grant of a United States Letters Patent on this invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1. FULL NAME OF SOLE OR FIRST INVENTOR	INVENTOR'S SIGNATURE	DATE
Maurice Bourlion		
RESIDENCE	CITIZENSHIP	
Saint-Chamond, France	France	
POST OFFICE ADDRESS		
9 rue Jean Vincent, F-42400 Saint-Chamond, France		
2. FULL NAME OF JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
Gerard Venacker		
RESIDENCE	CITIZENSHIP	
Tiburon, California, U.S.A	France	
POST OFFICE ADDRESS		
4131 Paradise Drive, US- 94920 Tiburon, California, U.S.A.		
3. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
Dominique Petit		
RESIDENCE	CITIZENSHIP	
Verton, France	France	
POST OFFICE ADDRESS		
2 rue des Peupliers, F-62180 Verton, France		
4. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
5. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
6. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
7. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

BDM-06-1214

ASSIGNMENT

WHEREAS, we, Maurice Bourlion, Gerard Vanacker and Dominique Petit, citizens of France, residing at 9 rue Jean Vincent, F-42400 Saint-Chamond, France; 4131 Paradise Drive, US-94920 Tiburon, California, U.S.A. and 2 rue des Peupliers, F-62180 Verton, France, respectively, (hereinafter referred to as "the undersigned"), having made an invention entitled DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE for which on the date set forth below, unless otherwise indicated here, _____, the undersigned executed an application for United States Letters Patent,

WHEREAS, Spinevision. a corporation of France, with offices at 180 avenue Daumesnil, F-75012 Paris, France (hereinafter referred to as "assignee"), is desirous of acquiring the entire right, title and interest in said invention, said application and all letters patent issuing for said invention,

NOW, THEREFORE, in consideration of One Dollar ($1.00) and of other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the assignee the entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said patent application, all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all letters patent and reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that the undersigned shall be legally bound, upon request of the assignee, or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments proper to patent the invention in the United States of America and foreign countries in the name of the assignee, and to execute all instruments proper to carry out the intent of this instrument. If the undersigned includes more than one individual, these obligations shall apply to all of the undersigned both individually and collectively.

The rights and property herein conveyed by the undersigned are free and clear of any encumbrance.

EXECUTED on _____, 20__, at _____.

_____
Maurice Bourlion

_____
Gerard Vanacker

_____
Dominique Petit

_____
Witness

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété Intellectuelle
Bureau international

(43) Date de la publication internationale
25 août 2005 (25.08.2005)

PCT

(10) Numéro de publication internationale
WO 2005/077283 A1

(51) Classification internationale des brevets⁷ : A61B 17/16

(21) Numéro de la demande internationale :
PCT/FR2005/000340

(22) Date de dépôt international :
11 février 2005 (11.02.2005)

(25) Langue de dépôt : français

(26) Langue de publication : français

(30) Données relatives à la priorité :
0401362 11 février 2004 (11.02.2004) FR

(71) Déposant *(pour tous les États désignés sauf US)* : SPINEVISION [FR/FR]; 180, avenue Daumesnil, F-75012 Paris (FR).

(72) Inventeurs; et

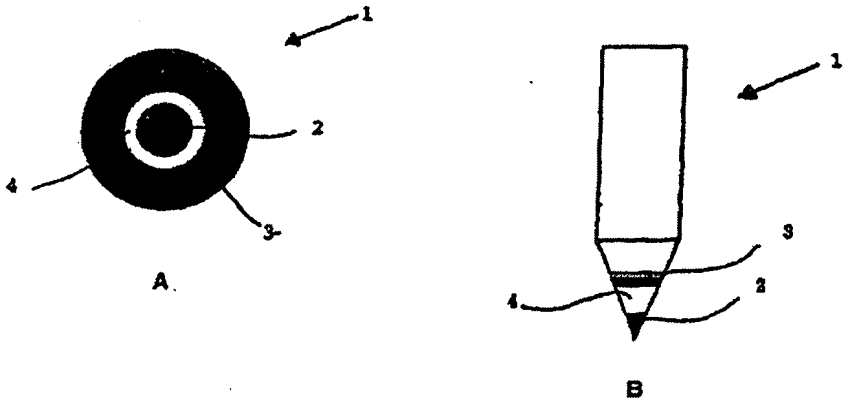
(75) Inventeurs/Déposants *(pour US seulement)* : BOURLION, Maurice [FR/FR]; 9, rue Jean Vincent, F-42400 Saint-Chamond (FR). VANACKER, Gérard [FR/FR]; 52, avenue François Adam, F-94100 Saint-Maur (FR). PETIT, Dominique [FR/FR]; 2, rue des Peupliers, F-62180 Verton (FR).

(74) Mandataire : SAYETTAT, Julien; Breesé Derambure Majerowicz, 38, avenue de l'Opéra, F-75002 Paris (FR).

[Suite sur la page suivante]

(54) Title: DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE

(54) Titre : DISPOSITIF POUR LE SUIVI DE LA PENETRATION D'UN INSTRUMENT DANS UNE STRUCTURE ANATOMIQUE



(57) Abstract: The invention relates to a device for monitoring the penetration of an instrument (1) into an anatomical structure, particularly a bone structure. The inventive device comprises a voltage source which powers at least two electrodes and a means for measuring the impedance between said electrodes. The invention is characterised in that the electrodes (2, 3) are located on the penetrating instrument (1) such as to present a flush constant contact surface that is dependent on how far the penetrating instrument (1) is inserted into the bone structure.

(57) Abrégé : La présente invention se rapporte à un dispositif pour le suivi de la pénétration d'un instrument (1) dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes et un moyen de mesure de l'impédance entre lesdites électrodes, caractérisé en ce que lesdites électrodes

[Suite sur la page suivante]

WO 2005/077283 A1

(81) **États désignés** *(sauf indication contraire, pour tous titre de protection nationale disponible)* : AB, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **États désignés** *(sauf indication contraire, pour tous titre de protection régionale disponible)* : ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publiée :

— *avec rapport de recherche internationale*

— *avant l'expiration du délai prévu pour la modification des revendications, sera republiée si des modifications sont reçues*

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

(2, 3) sont situées sur ledit instrument de pénétration (1) façon à présenter une surface de contact affleurante et constante en fonction du degré d'enfoncement dudit instrument de pénétration (1) dans ladite structure osseuse.

DISPOSITIF POUR LE SUIVI DE LA PÉNÉTRATION D'UN INSTRUMENT DANS UNE STRUCTURE ANATOMIQUE

La présente invention concerne le domaine de la chirurgie rachidienne, et plus particulièrement le suivi des instruments de pénétration au cours des opérations de perçage vertébral, cervical, thoracique, lombaire, sacré ou ilio sacré.

L'art antérieur connaît déjà des dispositifs permettant le suivi de la pénétration d'un instrument dans une structure anatomique, en particulier une structure osseuse.

On connaît le brevet européen EP0607688 décrivant une procédure et un système d'insertion d'une vis vertébrale pédiculaire, consistant à appliquer un potentiel électrique à la surface de la cavité, et à observer les réactions musculaires provoquées par cette stimulation.

On connaît également une solution consistant à mesurer la modification d'impédance dans la région voisine de la cavité osseuse explorée, à l'aide d'une sonde présentant une électrode venant en contact avec la paroi de la cavité osseuse, et une deuxième électrode placée sur le patient. Le but est de détecter des brèches dans la matière osseuse, par exemple lors d'une opération de préparation de la pose d'une vis pédiculaire dans une vertèbre.

L'information recueillie avec une telle solution est difficile à interpréter, car l'impédance mesurée entre les deux électrodes est perturbée par des artefacts liés à la variation d'enfoncement de la sonde dans la cavité. Les résistivités de l'air, des tissus musculaires, des tissus osseux et des brèches sont différentes, et le signal mesuré est une résultante de plusieurs paramètres masquant en partie l'information utile correspondant au passage de l'électrode de la sonde à proximité d'une brèche.

En outre, le dispositif proposé reste peu pratique du fait qu'il est nécessaire d'effectuer préalablement un calibrage (référence liée aux tissus mous).

Enfin, un tel dispositif reste de manipulation peu aisée du fait de la présence de câblages externes.

Le but de l'invention est de remédier à ces inconvénients en proposant un dispositif amélioré, dont le signal de sortie n'est pas perturbé par les variations dues à la profondeur d'engagement de l'instrument de pénétration.

La présente invention a également pour but de proposer un dispositif autonome, ne nécessitant aucun câblage externe.

La présente invention a également pour but de proposer un dispositif offrant des conditions de forage améliorées et sécurisées en avertissant l'opérateur de la formation de brèches.

À cet effet, l'invention concerne selon son acception la plus générale un dispositif pour le suivi de la pénétration d'un instrument dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes située sur ledit instrument et un moyen de mesure de l'impédance entre lesdites électrodes, et elle est remarquable en ce que lesdites électrodes sont situées sur ledit instrument de pénétration de façon à présenter une surface de contact affleurante et constante en fonction du degré d'enfoncement dudit instrument de pénétration dans ladite structure osseuse.

Plus précisément, la constance de la surface de contact des électrodes au cours de l'enfoncement dudit instrument de pénétration est obtenue de par les dimensions de ladite surface au regard des dimensions du trou formé dans la structure osseuse par ledit instrument de

pénétration, ladite surface de contact devant présenter des dimensions inférieures à celles du trou formé par ledit instrument de pénétration.

Par la notion de « surface de contact », il doit donc être compris le fait que la surface affleurante des électrodes présente des dimensions inférieures aux dimensions du trou formé par ledit instrument de pénétration.

De préférence, ledit dispositif comporte une électrode affleurant la surface distale dudit instrument de pénétration.

Par surface distale, on entend la surface de l'extrémité distale dudit instrument de pénétration.

Selon une première variante de l'invention, ledit dispositif comporte deux électrodes affleurant la surface distale dudit instrument de pénétration, lesdites électrodes étant disposées coaxialement et séparées l'une de l'autre par un isolant.

Selon une variante de réalisation de l'invention, ledit dispositif comporte deux électrodes affleurant la surface distale dudit instrument de pénétration, lesdites électrodes étant disposées l'une par rapport à l'autre symétriquement par rapport à l'axe longitudinal dudit instrument de pénétration.

Selon une autre variante de réalisation de l'invention, ledit dispositif comporte une pluralité d'électrodes affleurant la surface distale dudit instrument de pénétration.

Selon un mode de réalisation avantageux de l'invention, ledit dispositif comporte au moins une électrode présentant une surface de contact affleurant latéralement ledit instrument de pénétration.

Avantageusement, ladite électrode au moins présente une surface de contact annulaire.

Avantageusement, ledit dispositif comporte au moins deux électrodes présentant une surface de contact latérale annulaire.

Avantageusement, ledit dispositif comporte une électrode principale affleurant la surface distale dudit instrument de pénétration ainsi qu'une pluralité d'électrodes secondaires affleurant latéralement pour former des contacts annulaires espacés longitudinalement.

Selon un mode de réalisation préféré de l'invention, ledit dispositif comporte en outre des moyens de signalisation produisant un signal lors de la détection d'une variation de l'impédance par ledit moyen de mesure.

Avantageusement, le signal produit est un signal sonore dont la fréquence et/ou la cadence diminue(nt) en fonction de l'impédance mesurée. De préférence, la fréquence et/ou la cadence diminue(nt) non linéairement en fonction de l'impédance mesurée.

Ainsi, lorsque ledit instrument sort de la structure osseuse, le signal produit est un signal sonore aiguë à cadence rapide ; lorsque ledit instrument pénètre et reste dans la structure osseuse, le signal produit est un signal sonore grave à faible cadence.

Avantageusement, ledit dispositif comporte un canal central pour le passage d'un instrument additionnel.

L'invention sera mieux comprise à la lecture de la description qui suit, se référant aux figures annexées où :

- les figures 1A et 1B illustrent respectivement une vue en coupe frontale et une vue en coupe longitudinale d'un instrument de forage constituant un dispositif d'exploration de l'invention ;
- la figure 2 illustre une vue en coupe frontale d'une première variante de réalisation de l'instrument de forage ;

- la figure 3 illustre une représentation graphique du signal sonore émis par le dispositif d'exploration en fonction de l'impédance mesurée ;
- la figure 4 illustre une vue en coupe longitudinale d'une seconde variante de réalisation de l'instrument de forage ;
- la figure 5 illustre une vue en perspective d'une troisième variante de réalisation de l'instrument de forage ;
- la figure 6 illustre une vue en coupe longitudinale d'un instrument de pénétration constitué d'un taraud ; et
- la figure 7 illustre une vue en coupe longitudinale de l'instrument de pénétration selon une autre variation de l'instrument de forage.

Le dispositif selon l'invention est un dispositif permettant le suivi de la pénétration d'un instrument dans les structures osseuses d'un corps humain ou animal, lesdites structures présentant au moins deux zones d'impédance électrique différentes.

Lesdites électrodes, situées sur ledit instrument de pénétration (1), sont configurées pour présenter une surface de contact restant constante au cours de la pénétration dudit instrument de pénétration.

Lesdites électrodes sont reliées chacune à un générateur électrique délivrant une tension alternative, lequel comprend un circuit de mesure de l'impédance entre les deux électrodes (impédancemètre).

Ainsi, l'impédance des tissus pédiculaires étant strictement supérieure à celle des tissus musculaires, la détection d'une brèche se traduit par une diminution de l'impédance.

Ledit dispositif comporte en outre des moyens de signalisation produisant un signal spécifique lors de la

détection, par l'impédancemètre, d'une variation d'impédance, et donc de la pénétration de l'instrument dans une zone de tissus mous (moelle, nerfs), pour former ainsi une brèche dans le cortex osseux. Lesdits moyens de signalisation consistent en l'émission d'un signal visuel, tel qu'un témoin lumineux, d'un signal sonore, et/ou d'un signal tactile (vibreur, ...).

Un exemple préféré du principe de fonctionnement de la signalisation de la détection d'une brèche est décrit plus loin (figure 3).

Dans la partie ci-après, l'instrument de pénétration consiste en un instrument de forage (1). Cependant les configurations présentées ci-dessous sont bien entendu applicables aux autres instruments de pénétration (taraudage, curetage, spatulage, ...).

Les figures 1A et 1B illustrent une première configuration de l'instrument de forage (1) constituant ledit dispositif d'exploration selon l'invention.

Dans cette première configuration, l'instrument de forage (1) présente au niveau de son extrémité distale, deux électrodes (2, 3) de section circulaire et concentrique, l'électrode (2) intérieure étant séparée de l'électrode (3) extérieure par une couronne d'isolant (4).

L'électrode (2) constitue, dans cet exemple de réalisation, le pôle positif dudit dispositif électronique, l'électrode (3) le pôle négatif. Il est bien entendu évident qu'il ne s'agit ici que d'un exemple de réalisation, et que l'homme du métier pourra réaliser un dispositif électronique dont le pôle positif sera constitué par l'électrode (3) et le pôle négatif par l'électrode (2) sans pour autant sortir de l'invention.

Chaque électrode (2, 3) est disposée de sorte à affleurer la surface distale dudit instrument de forage (1).

Afin d'éviter toute perturbation du signal, la surface de l'électrode (3) affleurant la surface dudit instrument de forage (1) reste relativement petite par rapport aux dimensions du trou effectué dans le cortex osseux lors de l'opération de forage.

Lors de la pénétration de l'instrument (1) dans la structure osseuse, un signal est émis par lesdits moyens de signalisation lorsqu'une variation d'impédance mesurée entre lesdites électrodes (2, 3) est détectée par l'impédancemètre, indiquant la formation d'une brèche

A cet instant, le praticien est informé que l'extrémité de l'instrument de forage (1) vient de sortir du cortex osseux pour pénétrer dans une zone de tissus mous. Le praticien, s'il le souhaite, modifie alors la trajectoire de l'instrument de forage (1) de sorte à revenir dans le cortex osseux.

La figure 2 illustre une seconde configuration de l'instrument de forage (1) constituant ledit dispositif d'exploration.

Dans cette seconde configuration, l'instrument de pénétration (1) présente au niveau de son extrémité distale deux électrodes (2, 3) de section circulaire sensiblement identique. Lesdites électrodes (2, 3) sont avantageusement disposées symétriquement par rapport à l'axe longitudinal de l'instrument de forage (1).

La position desdites électrodes (2, 3) étant connue, leur disposition sur l'extrémité distale donne des indications sur la position des brèches. En effet, la brèche détectée sera située entre les deux électrodes (2, 3) pour lesquelles un signal est émis.

Le nombre et la forme des électrodes étant donné ici à titre d'exemple, il est entendu que ledit instrument (1) de pénétration peut présenter des électrodes en nombre

supérieur et de forme différente. Il est à noter que la détection volumétrique de brèches sera d'autant plus précise que le nombre d'électrodes réparties à l'extrémité dudit instrument (1) sera élevé.

La figure 3 illustre la représentation graphique de la fréquence et/ou cadence d'un signal sonore émis par lesdits moyens de signalisation en fonction de l'impédance mesurée entre les électrodes.

Selon un mode de réalisation préférentiel de l'invention, la courbe correspondant à la fréquence et/ou la cadence du signal émis en fonction de l'impédance est décroissante et non linéaire (cf. figure 3). Ainsi, lorsque l'instrument de pénétration est situé dans le cortex osseux, l'impédance mesurée entre les électrodes correspond à l'impédance de l'os, cette impédance restant relativement constante. Lesdits moyens de signalisation informent le praticien de la position correcte dans le cortex par l'émission d'un signal de fréquence grave et de cadence lente. En particulier, au-delà d'une certaine valeur de l'impédance, correspondant à l'impédance mesurée dans l'os, la fréquence ainsi que la cadence des signaux restent relativement constantes.

En revanche, lorsque l'extrémité de l'instrument pénètre dans un tissu environnant mou, le praticien en est averti par une augmentation de la fréquence et une accélération de la cadence du signal.

Ainsi, suivant cette configuration, une faible variation de l'impédance dans l'os ne s'entendra pas alors que, toute variation d'impédance liée à la pénétration de l'instrument dans un tissu environnant mou, aussi faible soit elle, s'entendra fortement.

De la même façon, il est possible de réaliser des instruments de pénétration présentant d'autres fonctionnalités.

En particulier, ledit instrument (1) de forage pourra avantageusement comporter au moins une électrode (7) affleurant la surface latérale dudit instrument (1) de forage, ainsi que deux électrodes (5, 6) disposées concentriquement à l'extrémité distale dudit instrument (1) de forage (figure 7). Il sera ainsi possible, de par la configuration dudit instrument (1) de forage, de déterminer la présence et la direction d'une brèche au moyen des électrodes (6, 7), ainsi que de prévenir une éventuelle perforation du cortex osseux au moyen des électrodes (5, 6). A cet effet, il devra être évité de positionner une électrode latérale consistant en une tige allant jusqu'à l'extrémité distale. Il serait en effet impossible, avec une telle configuration, de savoir si la zone détectée par les électrodes est latérale ou distale.

Avantageusement, des électrodes pourront être disposées sur la surface latérale de l'instrument de forage pour former des bandes de contact annulaires affleurant la surface de l'instrument de forage (1) (figure 4).

Selon une variante de réalisation de l'invention, les électrodes seront avantageusement disposées sous la forme de points de contact répartis de façon homogène sur la surface de l'instrument de forage (1), une telle répartition des électrodes permettant une détection volumétrique des perforations (figure 5). Une telle configuration permet ainsi d'informer à chaque instant le chirurgien de la zone d'impédance la plus faible.

La figure 6 illustre également la réalisation d'un instrument de pénétration configuré pour le taraudage.

Avantageusement, ledit instrument (1) est constitué d'une extrémité distale en forme de pointe et présente sur sa paroi latérale des arêtes coupantes. Une électrode (3) est disposée sur au moins une arête coupante. Au moins une autre électrode (2) est également disposée à l'extrémité distale en forme de pointe dudit instrument (1). Ainsi, lors de l'opération de taraudage, le chirurgien est informé en temps réel de la formation d'une brèche non seulement en bout de l'instrument et provoquée par l'extrémité distale en forme de pointe de l'instrument (1), mais également latéralement par rapport à la paroi dudit instrument (1) et provoquée par au moins une des arêtes coupantes. .

L'invention est décrite dans ce qui précède à titre d'exemple. Il est entendu que l'homme du métier est à même de réaliser différentes variantes de l'invention sans pour autant sortir du cadre du brevet.

REVENDICATIONS

1. Dispositif pour le suivi de la pénétration d'un instrument (1) dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes et un moyen de mesure de l'impédance entre lesdites électrodes, caractérisé en ce que lesdites électrodes (2, 3) sont situées sur ledit instrument de pénétration (1) de façon à présenter une surface de contact affleurante et constante en fonction du degré d'enfoncement dudit instrument de pénétration (1) dans ladite structure osseuse.

2. Dispositif selon la revendication 1, caractérisé en ce qu'il comporte une électrode affleurant la surface distale dudit instrument de pénétration (1).

3. Dispositif selon la revendication 1 ou la revendication 2, caractérisé en ce qu'il comporte deux électrodes affleurant la surface distale dudit instrument de pénétration (1), lesdites électrodes étant disposées coaxialement et séparées l'une de l'autre par un isolant (4).

4. Dispositif selon la revendication 1 ou la revendication 2, caractérisé en ce qu'il comporte deux électrodes affleurant la surface distale dudit instrument de pénétration (1), lesdites électrodes étant symétriques par rapport à l'axe longitudinal dudit instrument de pénétration.

5. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce qu'il comporte une pluralité d'électrodes affleurant la surface distale dudit instrument de pénétration (1).

6. Dispositif selon la revendication 1, caractérisé en ce qu'il comporte au moins une électrode présentant une surface de contact affleurant latéralement ledit instrument de pénétration (1).

7. Dispositif selon la revendication précédente, caractérisé en ce que ladite électrode au moins présente une surface de contact annulaire.

8. Dispositif selon la revendication 6 ou la revendication 7, caractérisé en ce qu'il comporte au moins deux électrodes présentant une surface de contact latérale annulaire.

9. Dispositif selon la revendication 1, caractérisé en ce qu'il comporte une électrode principale affleurant la surface distale dudit instrument de pénétration (1) ainsi qu'une pluralité d'électrodes secondaires affleurant latéralement pour former des contacts annulaires espacés longitudinalement.

10. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce qu'il comporte en outre des moyens de signalisation produisant un signal lors de la détection par ledit moyen de mesure de l'impédance une variation de l'impédance.

11. Dispositif selon la revendication précédente, caractérisé en ce que le signal produit est un signal sonore dont la fréquence et/ou la cadence diminue(nt) en fonction de l'impédance mesurée.

12. Dispositif selon la revendication précédente, caractérisé en ce que la fréquence et/ou la cadence

diminue(nt) non linéairement en fonction de l'impédance mesurée.

13. Dispositif selon l'une quelconque des revendications 10 à 12, caractérisé en ce que le signal produit lorsque ledit instrument sort de la structure osseuse est un signal sonore aiguë à cadence rapide.

14. Dispositif selon l'une quelconque des revendications 10 à 12, caractérisé en ce que le signal produit lorsque ledit instrument pénètre la structure osseuse est un signal sonore grave à faible cadence.

15. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que ledit dispositif est un dispositif autonome.

16. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce qu'il comporte un canal central pour le passage d'un instrument additionnel.

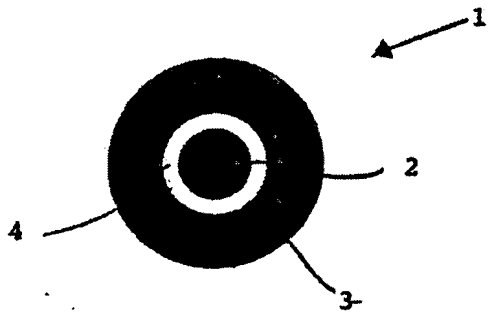


Fig. 1A

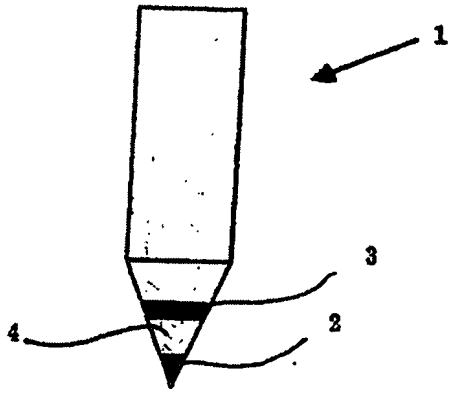


Fig. 1B

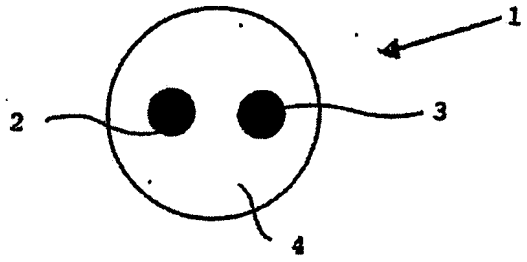


Fig. 2

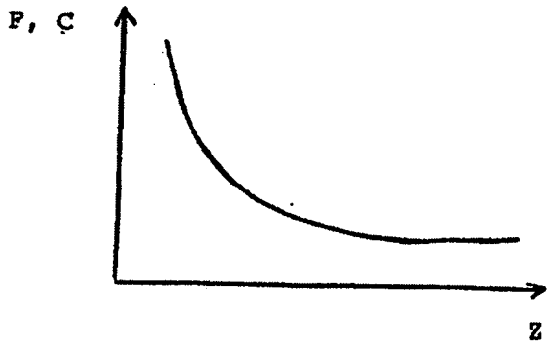


Fig. 3

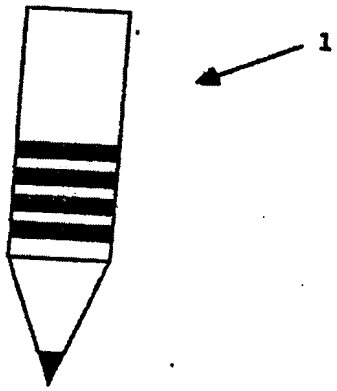


Fig. 4

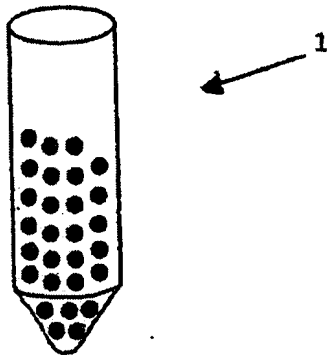


Fig. 5

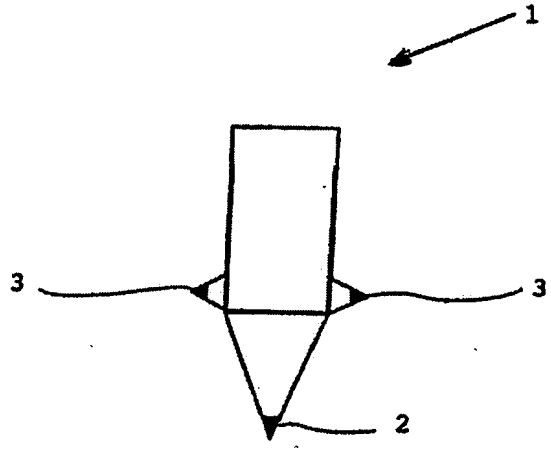


Fig. 6

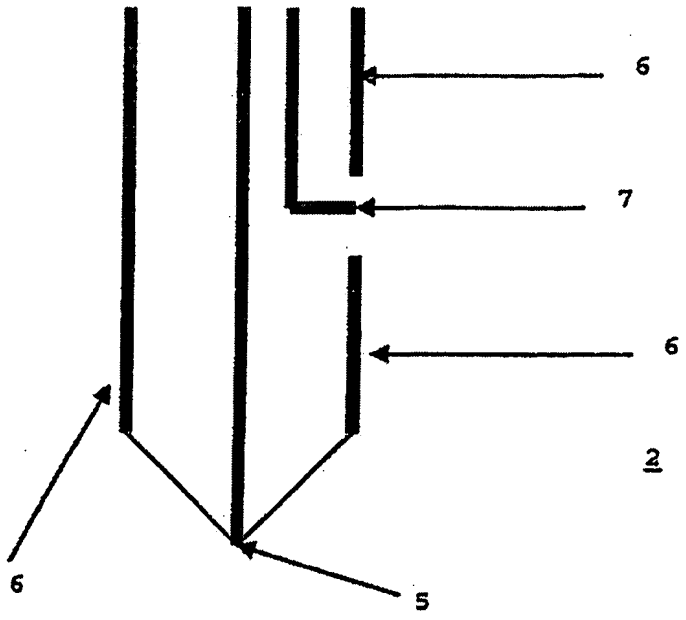


Fig. 7

EMC: EV 548524561 US

DEVICE TO MONITOR THE PENETRATION OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE

[0001] The present invention concerns the domain of spinal surgery, and more particularly the monitoring of penetration instruments during operations of vertebral, cervical, thoracic, lumbar, sacral or ilio-sacral drilling.

[0002] The prior art is already familiar with devices used to follow the penetration of an instrument in an anatomic structure, in particular a bone structure.

[0003] We are aware of European patent EP0607688 describing a procedure and a system for the insertion of a pedicular vertebral screw, consisting of applying an electric potential to the surface of the cavity, and observing the muscular reactions provoked by this stimulation.

[0004] We are also aware of a solution consisting of measuring the modification in the impedance of the region neighbouring the explored bone cavity, using a sound presenting an electrode coming into contact with the wall of the bone cavity, and a second electrode placed on the patient. The purpose is to detect the gaps in bone matter, for example during an operation preparing for the insertion of a pedicular screw in a vertebra.

[0005] The information gathered with such a solution is difficult to interpret, since the impedance measured between the two electrodes is perturbed by artefacts related to the variation in the penetration of the sound in the cavity. The resistivities of the air, muscle tissue, bone tissue and gaps differ, and the signal measured is the result of several parameters that in part mask the useful information corresponding to the passage of the electrode of the sound near a gap.

[0006] In addition, the device proposed is not very practical since it first requires a calibration (reference related to soft tissue).

[0007] Finally, such a device remains not very easy to manipulate due to the presence of external cables.

[0008] The purpose of the invention is to correct these disadvantages by proposing an improved device, whose output signal is not disturbed by variations due to the depth of the entry of the penetration instrument.

[0009] The present invention also aims at proposing an autonomous device, not requiring external cabling.

[0010] The present invention also aims at proposing a device offering improved and safer drilling conditions by informing the operator of the formation of gaps.

[0011] For this purpose, according to its most general acceptation, the invention concerns a device to monitor the penetration of an instrument in an anatomic structure, in particular a bone structure, comprising a source of current supplying at least two electrodes located on the aforementioned instrument and a means to measure the impedance between the aforementioned electrodes, and it is remarkable in that the aforementioned electrodes are located on the aforementioned penetration instrument so as to present a coinciding and constant contact surface as a function of the degree of entry of the aforementioned penetration instrument in the aforementioned bone structure.

[0012] More precisely, the invariability of the contact surface of the electrodes during the entry of the aforementioned penetration instrument is obtained by the dimensions of the aforementioned surface with respect to the dimensions of the hole formed in the bone structure by the aforementioned penetration instrument, since the dimensions of the aforementioned contact surface should not exceed those of the hole formed by the aforementioned penetration instrument.

[0013] The term "contact surface" refers to the fact that the dimensions of the surface coinciding with the electrodes is smaller than those of the hole formed by the aforementioned penetration instrument.

[0014] Preferably, the aforementioned device comprises an electrode coinciding with the distal surface of the aforementioned penetration instrument.

[0015] Distal surface refers to the surface of the distal end of the aforementioned penetration instrument.

[0016] According to a first variant of the invention, the aforementioned device comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument, since the aforementioned electrodes are coaxially placed and separated by an insulation.

[0017] According to one variant of the invention, the aforementioned device comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument, since the aforementioned electrodes are symmetrically placed with respect to a longitudinal axis of the aforementioned penetration instrument.

[0018] According to another variant of the invention, the aforementioned device comprises a plurality of electrodes coinciding with the distal surface of the aforementioned penetration instrument.

[0019] According to an advantageous mode of implementation of the invention, the aforementioned device comprises at least one electrode presenting a contact surface laterally coinciding with the aforementioned penetration instrument.

[0020] Advantageously, the aforementioned electrode at least presents an annular contact surface.

[0021] Advantageously, the aforementioned device comprises at least two electrodes presenting an annular lateral contact surface.

[0022] Advantageously, the aforementioned device comprises a main electrode coinciding with the distal surface of the aforementioned penetration instrument as well as a plurality of secondary laterally coinciding electrodes to form longitudinally spaced annular contacts.

[0023] According to a preferred mode of implementation of the invention, the aforementioned device also comprises means of signalling producing a signal at the time of detection of a variation in the impedance by the aforementioned means of measurement.

[0024] Advantageously, the signal produced is a sound signal whose frequency and/or rhythm decreases as a function of the impedance measured. Preferably, the frequency and/or rhythm non linearly reduce as a function of the impedance measured.

[0025] Therefore, when the aforementioned instrument leaves the bone structure, an acute sound signal with a rapid rhythm is produced. When the aforementioned instrument penetrates and remains in the bone structure, a low-pitched sound signal with a low rhythm is produced.

[0026] Advantageously, the aforementioned device comprises a central channel for the passage of an additional instrument.

[0027] The invention will be better understood upon reading the following description, referring to the appended figures where:

- figures 1A and 1B respectively illustrate a front section view and a longitudinal section view of a drilling instrument forming the exploration device of the invention;
- figure 2 illustrates a front section view of a first variant of the drilling instrument;
- figure 3 illustrates a graphic representation of the sound signal given off by the exploration device as a function of the impedance measured;

- figure 4 illustrates a longitudinal section view of a second variant of the drilling instrument;
- figure 5 illustrates a perspective view of a third variant of the drilling instrument;
- figure 6 illustrates a longitudinal section view of a penetration instrument comprising a tap; and
- figure 7 illustrates a longitudinal section view of the penetration instrument according to another variation of the drilling instrument.

[0028] The device according to the invention is a device to monitor the penetration of an instrument in the bone structures of a human or animal body, the aforementioned structures presenting at least two different zones of electric impedance.

[0029] The aforementioned electrodes, located on the aforementioned penetration instrument (1), are configured to present a contact surface that remains constant during the penetration of the aforementioned penetration instrument.

[0030] The aforementioned electrodes are each connected to an electric generator delivering an alternative current, which comprises a circuit to measure the impedance between the two electrodes (impedometer).

[0031] Therefore, since the impedance of the pedicular tissue is strictly superior that of muscle tissue, the detection of a gap results in a reduction in the impedance.

[0032] The aforementioned device also comprises means of signalling producing a specific signal at the time of the detection, by impedometer, of a variation in impedance, and therefore the penetration of the instrument in a zone of soft tissue (marrow, nerves), to thereby form a gap in the bone cortex. The aforementioned means of signalling consist of the emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, -).

[0033] A preferred example of the operating principle of the signalling of the detection of a gap is described below (figure 3).

[0034] In the following section, the penetration instrument consists of a drilling instrument (1). However, the configurations presented below are of course applicable to other penetration instruments (tapping, curettage, spatulage, -).

[0035] Figures 1A and 1B illustrate a first configuration of the drilling instrument (1) composing the aforementioned exploration device according to the invention.

[0036] In this first configuration, the drilling instrument (1) has, at the distal end, two electrodes (2, 3) of circular and concentric section, inner electrode (2) being separated from outer electrode (3) by an insulation ring (4).

[0037] Electrode (2) comprises, in this example of implementation, the positive pole of the aforementioned electronic device, electrode (3) the negative pole. It is of course obvious that this is only an example of implementation, and that the man skilled in the art may create an electronic device whose positive pole will consist of electrode (3) and negative pole of electrode (2) without going beyond the invention.

[0038] Each electrode (2, 3) is arranged so as to coincide with the distal surface of the aforementioned drilling instrument (1).

[0039] In order to avoid any perturbation in the signal, the surface of electrode (3) coinciding with the surface of the aforementioned drilling instrument (1) remains relatively small compared with the dimensions of the hole made in the bone cortex during the drilling operation.

[0040] During the penetration of the instrument (1) in the bone structure, a signal is given off by the aforementioned means of signalling when a variation in the impedance measured between

the aforementioned electrodes (2, 3) is detected by the impedometer, indicating the formation of a gap.

[0041] At that time, the practitioner is informed that the end of the drilling instrument (1) has just left the bone cortex to penetrate in a zone of soft tissue. The practitioner, if he so desires, then modifies the path of the drilling instrument (1) so as to return to the bone cortex.

[0042] Figure 2 illustrates a second configuration of the drilling instrument (1) comprising the aforementioned exploration device.

[0043] In this second configuration, the penetration instrument (1) presents two electrodes (2, 3) of sensibly identical circular section its the distal end. The aforementioned electrodes (2, 3) are advantageously symmetrically arranged with respect to the longitudinal axis of the drilling instrument (1).

[0044] Since the position of the aforementioned electrodes (2, 3) is known, their disposition on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes (2, 3) for which a signal is emitted.

[0045] Since the number and shape of the electrodes is here provided by way of example, it is understood that the aforementioned penetration instrument (1) may present a greater number of electrodes and their shape may differ. It should be noted that the volumetric detection of gaps will be more exact the higher the number of electrodes distributed at the end of the aforementioned instrument (1).

[0046] Figure 3 illustrates the graphic representation of the frequency and/or rhythm of a sound signal given off by the aforementioned means of signalling as a function of the impedance measured between the electrodes.

[0047] According to one preferential mode of implementation of the invention, the curve corresponding to the frequency and/or rhythm of the signal emitted as a function of the impedance is decreasing and not linear (see figure 3). Therefore, when the penetration instrument is located in the bone cortex, the impedance measured between the electrodes corresponds to the impedance of the bone, this impedance remains relatively constant. The aforementioned means of signalling inform the practitioner of the proper position in the cortex by the emission of a signal with a low frequency and slow rhythm. In particular, beyond a certain value of impedance, corresponding to the impedance measured in the bone, the frequency as well as the rhythm of the signal remain relatively constant.

[0048] However, when the end of the instrument enters surrounding soft tissue, the practitioner is informed of this by an increase in the frequency and an acceleration in the rhythm of the signal.

[0049] Therefore, following this configuration, a small variation of the impedance in the bone is not heard while any variation in the impedance related to the penetration of the instrument in the surrounding soft tissue, as small as it may be, will be strongly heard.

[0050] In the same way, it is possible to create penetration instruments presenting other functionalities.

[0051] In particular, the aforementioned drilling instrument (1) may advantageously comprise at lease one electrode (7) coinciding with the lateral surface of the aforementioned drilling instrument (1), as well as two electrodes (5, 6) concentrically arranged at the distal end of the aforementioned drilling instrument (1) (figure 7). It will thereby be possible, due to the configuration of the aforementioned drilling instrument (1) to determine the presence and direction of a gap by means of electrodes (6, 7) as well as signal any perforation of the bone

cortex by means of electrodes (5, 6). For this purpose, the positioning of a lateral electrode consisting of a rod going to the distal end should be avoided. In fact, it would be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

[0052] Advantageously, the electrodes may be arranged on the lateral surface of the drilling instrument in order to form annular bands of contact coinciding with the surface of the drilling instrument (1) (figure 4).

[0053] According to one variant of the invention, the electrodes will be advantageously arranged in the form of points of contact distributed in a homogenous manner on the surface of the drilling instrument (1). Such a distribution of the electrodes will enable the volumetric detection of the perforations (figure 5). Such a configuration may thereby inform the surgeon of the lowest zone of impedance at all times.

[0054] Figure 6 also illustrates the implementation of a penetration instrument configured for tapping. Advantageously, the aforementioned instrument (1) comprises a distal end in the form of a point and the lateral wall presents cutting stops. One electrode (3) is arranged on at least one cutting stop. At least one other electrode (2) is also arranged at the distal end in point form of the aforementioned instrument (1). Therefore, during the tapping operation, the surgeon is informed of the formation of a gap in real time not only at the end of the instrument and provoked by the distal end in point form on the instrument (1) but also laterally with respect to the wall of the aforementioned instrument (1) and provoked by at least one of the cutting stops.

[0055] The invention is described above by way of example. It is understood that the man skilled in the art is able to create different variants of the invention without going beyond the framework of the patent.

CLAIMS

1. Device to monitor the penetration of an instrument (1) in an anatomic structure, in particular a bone structure, comprising a source of current supplying at least two electrodes and a means to measure the impedance between the aforementioned electrodes, characterised in that the aforementioned electrodes (2, 3) are located on the aforementioned penetration instrument (1) so as to present a coinciding and constant contact surface as a function of the degree of penetration of the aforementioned penetration instrument (1) in the aforementioned bone structure.

2. Device according to claim 1, characterised in that it comprises an electron coinciding with the distal surface of the aforementioned penetration instrument.

3. Device according to claim 1 or claim 2, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being coaxially arranged and separated from each other by an insulation.

4. Device according to claim 1 or claim 2, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being symmetrical with respect to the longitudinal axis of the aforementioned penetration instrument.

5. Device according to any of the previous claims, characterised in that it comprises a plurality of electrodes coinciding with the distal surface of the aforementioned penetration instrument (1).

6. Device according to claim 1, characterised in that it comprises at least one electrode presenting a contact surface laterally coinciding with the aforementioned penetration instrument (1).

7. Device according to the previous claim, characterised in that the aforementioned electrode at least presents one annular contact surface.

8. Device according to claim 6 or claim 7, characterised in that it comprises at least two electrodes presenting a lateral annular contact surface.

9. Device according to claim 1, characterised in that it comprises one main electrode coinciding with the distal surface of the aforementioned penetration instrument (1) as well as a plurality of laterally coinciding secondary electrodes to form longitudinally spaced annular contacts.

10. Device according to any of the previous claims, characterised in that it also comprises means of signalling producing a signal during the detection by the aforementioned means to measure the impedance by a variation in impedance.

11. Device according to the previous claims, characterised in that the signal produced is a sound signal whose frequency and/or rhythm decrease as a function of the impedance measured.

12. Device according to the previous claim, characterised in that the frequency and/or rhythm decrease in a non linear manner as a function of the impedance measured.

13. Device according to any of claims 10 to 12, characterised in that the signal produced when the aforementioned instrument leaves the bone structure is an acute sound signal with a rapid rhythm.

14. Device according to any of claims 10 to 12, characterised in that the signal produced when the aforementioned instrument penetrates the bone structure is a low-pitched sound signal with a slow rhythm.

15. Device according to any of the previous claims, characterised in that the aforementioned device is an autonomous device.

16. Device according to any of the previous claims, characterised in that it comprises a central channel for the passage of an additional instrument.

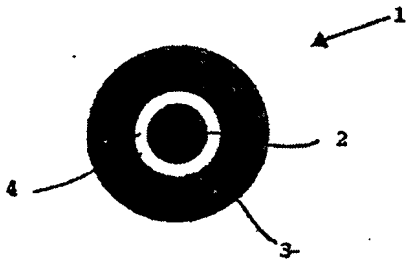


Fig. 1A

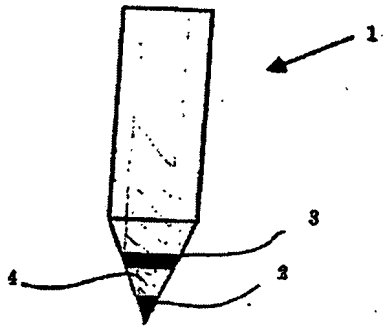


Fig. 1B

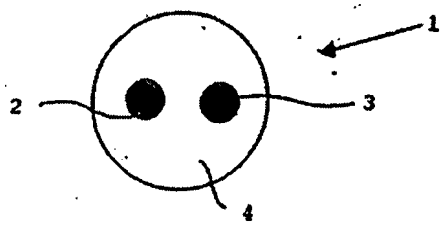


Fig. 2

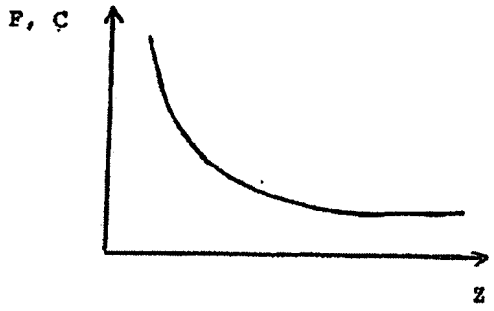


Fig. 3

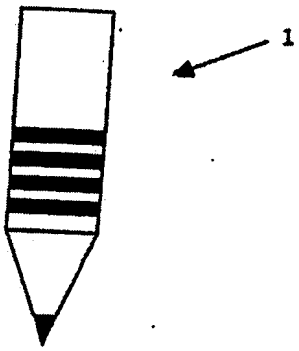


Fig. 4

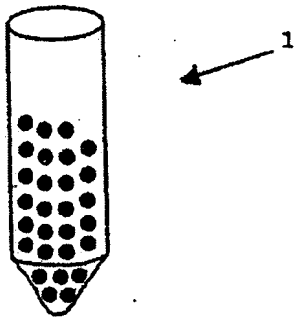


Fig. 5

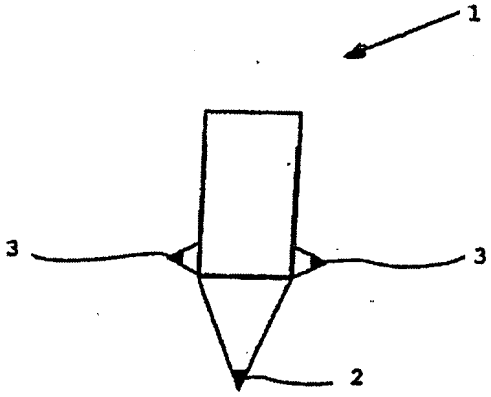


Fig. 6

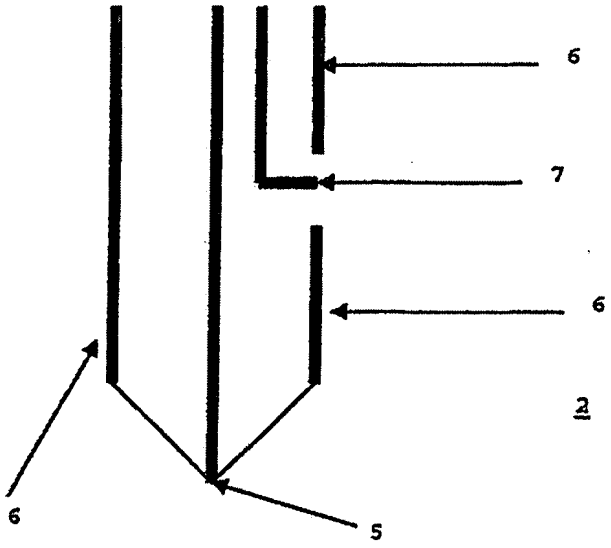


Fig. 7

CLAIMS

1. Device to monitor the penetration of an instrument (1) in an anatomic structure, in particular a bone structure, comprising a source of current supplying at least two electrodes and a means to measure the impedance between the aforementioned electrodes, the aforementioned electrodes (2, 3) are located on the aforementioned penetration instrument (1) characterised in that the device comprises at least a first electrode presenting a contact surface coinciding with the distal surface of the aforementioned penetration instrument and at least a second electrode presenting a contact surface coinciding with the lateral surface of the aforementioned penetration instrument (1), said contact surfaces dimension are so as to present a coinciding and constant contact surface as a function of the degree of penetration of the aforementioned penetration instrument (1) in the aforementioned bone structure.

2. Device according to claim 1, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being coaxially arranged and separated from each other by an insulation (4).

3. Device according to claim 1, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being symmetrical with respect to the longitudinal axis of the aforementioned penetration instrument.

4. Device according to any of the previous claims, characterised in that the aforementioned electrode at least presents one annular contact surface.

5. Device according to claim 1, characterised in that it comprises one main electrode coinciding with the distal surface of the aforementioned penetration instrument (1) as well as a plurality of laterally coinciding secondary electrodes to form longitudinally spaced annular contacts.

6. Device according to claim 1, characterised in that it comprises a first electrode coinciding with the distal surface of the aforementioned penetration instrument (1), a second electrode coinciding with the lateral surface of the aforementioned penetration instrument (1) and a third electrode partially covering lateral surface of the aforementioned penetration instrument (1).

7. Device according to any of the previous claims, characterised in that it also comprises means of signalling producing a signal during the detection by the aforementioned means to measure the impedance by a variation in impedance.

8. Device according to the previous claim, characterised in that the signal produced is a sound signal whose frequency and/or rhythm decrease as a function of the impedance measured.

9. Device according to the previous claim, characterised in that the frequency and/or rhythm decrease in a non linear manner as a function of the impedance measured.

10. Device according to any of claims 7 to 9, characterised in that the signal produced when the aforementioned instrument leaves the bone structure is an acute sound signal with a rapid rhythm.

11. Device according to any of claims 7 to 9, characterised in that the signal produced when the aforementioned instrument penetrates the bone structure is a low-pitched sound signal with a slow rhythm.

12. Device according to any of the previous claims, characterised in that the aforementioned device is an autonomous device.

13. Device according to any of the previous claims, characterised in that it comprises a central channel for the passage of an additional instrument.

Replacement Sheet

SUBSTITUTE SPECIFICATION (Clean Copy)

DEVICES THAT MONITOR PENETRATION OF AN INSTRUMENT IN AN ANATOMICAL STRUCTURE

Related Application

[0001] This is a §371 of International Application No. PCT/FR2005/000340, with an international filing date of February 11, 2005 (WO 2005/077283 A1, published August 25, 2005), which is based on French Patent Application No. 04/01362, filed February 11, 2004.

Technical Field

[0002] This disclosure relates to spinal surgery, more particularly, monitoring of penetration instruments during operations of vertebral, cervical, thoracic, lumbar, sacral or ilio-sacral drilling.

Background

[0003] Devices used to follow the penetration of an instrument in an anatomical structure, in particular, a bone structure are known.

[0004] Ep 0 607 688 describes a procedure and system for the insertion of a pedicular vertebral screw, incuding applying an electric potential to the surface of the cavity, and observing the muscular reactions provoked by this stimulation.

[0005] It is also known to measure the modification in the impedance of the region neighboring the explored bone cavity using a sound presenting an electrode coming into contact with the wall of the bone cavity, and a second electrode placed on the patient. The purpose is to

detect the gaps in bone matter, for example, during an operation preparing for the insertion of a pedicular screw in a vertebra.

[0006] The information gathered with such an approach is difficult to interpret since the impedance measured between the two electrodes is perturbed by artefacts related to the variation in the penetration of the sound in the cavity. The resistivities of the air, muscle tissue, bone tissue and gaps differ, and the signal measured is the result of several parameters that in part mask the useful information corresponding to the passage of the electrode of the sound near a gap.

[0007] In addition, the device is not very practical since it first requires calibration (reference related to soft tissue). Finally, such a device remains not very easy to manipulate due to the presence of external cables.

[0008] It could therefore be advantageous to provide a device whose output signal is not disturbed by variations due to the depth of the entry of the penetration instrument.

Summary

[0009] This invention relates to a device to monitor penetration of an instrument in an anatomical structure including at least two electrodes, a source of current supplying the at least two electrodes, and means for measuring impedance between the electrodes, wherein the electrodes are located on the penetration instrument, wherein the first electrode has a contact surface coinciding with a distal surface of the penetration instrument and the second electrode has a contact surface coinciding with a lateral surface of the penetration instrument, and wherein the contact surfaces are dimensioned to have a coinciding and constant contact surface as a function of a degree of penetration of the penetration instrument in the anatomical structure.

Brief Description of the Drawings

[0010] Selected, representative aspects of the devices will be better understood upon reading the following description, referring to the appended figures where:

Figs. 1A and 1B, respectively, are a front sectional view and a longitudinal sectional view of a drilling instrument forming an exploration device;

Fig. 2 is a front sectional view of a drilling instrument;

Fig. 3 is a graphic representation of the sound signal given off by the exploration device as a function of the impedance measured;

Fig. 4 is a longitudinal sectional view of a drilling instrument;

Fig. 5 is a perspective view of a drilling instrument;

Fig. 6 is a longitudinal sectional view of a penetration instrument comprising a tap; and

Fig. 7 is a longitudinal sectional view of a penetration instrument of a drilling instrument.

Detailed Description

[0011] We disclose devices to monitor penetration of an instrument in an anatomical structure, in particular, a bone structure, comprising a source of current supplying at least two electrodes located on the instrument and a means to measure the impedance between the electrodes. The electrodes are located on the penetration instrument to present a coinciding and constant contact surface as a function of the degree of entry of the penetration instrument in the bone structure.

[0012] More precisely, the invariability of the contact surface of the electrodes during entry of the penetration instrument is obtained by the dimensions of the surface with respect to the dimensions of the hole formed in the bone structure by the penetration instrument, since the

dimensions of the contact surface should not exceed those of the hole formed by the penetration instrument.

[0013] The term "contact surface" refers to the fact that the dimensions of the surface coinciding with the electrodes is smaller than those of the hole formed by the penetration instrument.

[0014] Preferably, the device comprises an electrode coinciding with the distal surface of the penetration instrument.

[0015] "Distal" surface refers to the surface of the distal end portion of the penetration instrument.

[0016] The device may comprise two electrodes coinciding with the distal surface of the penetration instrument, since the electrodes are substantially coaxially placed and separated by insulation.

[0017] The device may also comprise two electrodes coinciding with the distal surface of the penetration instrument since the electrodes are symmetrically placed with respect to a longitudinal axis of the penetration instrument.

[0018] The device may further comprise a plurality of electrodes coinciding with the distal surface of the penetration instrument.

[0019] The device may comprise at least one electrode having a contact surface laterally coinciding with the penetration instrument. Advantageously, the electrode at least has a substantially annular contact surface. Advantageously, the device comprises at least two electrodes having an annular lateral contact surface.

[0020] Advantageously, the device may comprise a main electrode coinciding with the distal surface of the penetration instrument as well as a plurality of secondary laterally coinciding electrodes to form longitudinally spaced annular contacts.

[0021] The device may also comprise means of signalling producing a signal at the time of detection of a variation in the impedance by the means of measurement.

[0022] Advantageously, the signal produced may be a sound signal whose frequency and/or rhythm decreases as a function of the impedance measured. Preferably, the frequency and/or rhythm non linearly reduce as a function of the impedance measured.

[0023] Therefore, when the instrument leaves the bone structure, an acute sound signal with a rapid rhythm is produced. When the instrument penetrates and remains in the bone structure, a low-pitched sound signal with a low rhythm is produced.

[0024] Advantageously, the device may comprise a central channel for the passage of an additional instrument.

[0025] The device monitors penetration of an instrument in the bone structures of a human or animal body, the structures having at least two different zones of electric impedance.

[0026] The electrodes, located on the penetration instrument (1), are configured to have a contact surface that remains constant during penetration of the penetration instrument.

[0027] The electrodes are each connected to an electric generator delivering an alternative current, which comprises a circuit to measure the impedance between the two electrodes (impedometer).

[0028] Therefore, since the impedance of the pedicular tissue is superior that of muscle tissue, the detection of a gap results in a reduction in the impedance.

[0029] The device also comprises means for signalling that produce a specific signal at the time of the detection, by impedometer, of a variation in impedance and, therefore, penetration of the instrument in a zone of soft tissue (marrow, nerves), to thereby form a gap in the bone cortex. The means for signalling include emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator or the like).

[0030] A preferred example of the operating principle of the signalling of the detection of a gap is described below and shown in Fig. 3.

[0031] In the following section, the penetration instrument includes a drilling instrument (1). However, the configurations presented below are, of course, applicable to other penetration instruments (tapping, curettage, spatulage and the like).

[0032] Figs. 1A and 1B illustrate a first configuration of the drilling instrument (1) composing the exploration device.

[0033] In this first configuration, the drilling instrument (1) has, at the distal end portion, two electrodes (2, 3) of circular and concentric section, inner electrode (2) being separated from outer electrode (3) by an insulation ring (4).

[0034] Electrode (2) comprises in this example the positive pole of the electronic device, electrode (3) the negative pole. This is only one example of implementation and one skilled in the art may create an electronic device whose positive pole will include electrode (3) and negative pole of electrode (2) without going beyond the scope of this disclosure.

[0035] Each electrode (2, 3) is arranged to coincide with the distal surface of the drilling instrument (1).

[0036] In order to avoid any perturbation in the signal, the surface of electrode (3) coinciding with the surface of the drilling instrument (1) remains relatively small compared with the dimensions of the hole made in the bone cortex during the drilling operation.

[0037] During penetration of the instrument (1) in the bone structure, a signal is given off by the means effor signalling when a variation in the impedance measured between the electrodes (2, 3) is detected by the impedometer, indicating formation of a gap.

[0038] At that time, the practitioner is informed that the end of the drilling instrument (1) has just left the bone cortex to penetrate in a zone of soft tissue. The practitioner, if so desired, then modifies the path of the drilling instrument (1) to return to the bone cortex.

[0039] Fig. 2 illustrates a second configuration of the drilling instrument (1) comprising the exploration device.

[0040] In this second configuration, the penetration instrument (1) has two electrodes (2, 3) of sensibly identical circular section its the distal end. The electrodes (2, 3) are advantageously symmetrically arranged with respect to the longitudinal axis of the drilling instrument (1).

[0041] Since the position of the electrodes (2, 3) is known, their disposition on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes (2, 3) for which a signal is emitted.

[0042] Since the number and shape of the electrodes is here provided by way of example, it is understood that the penetration instrument (1) may have a greater number of electrodes and their shape may differ. It should be noted that the volumetric detection of gaps will be more exact the higher the number of electrodes distributed at the end of the instrument (1).

[0043] Fig. 3 illustrates the graphic representation of the frequency and/or rhythm of a sound signal given off by the means for signalling as a function of the impedance measured between the electrodes.

[0044] According to one preferential mode of implementation, the curve corresponding to the frequency and/or rhythm of the signal emitted as a function of the impedance is decreasing and not linear as shown in Fig. 3. Therefore, when the penetration instrument is located in the bone cortex, the impedance measured between the electrodes corresponds to the impedance of the bone, this impedance remains relatively constant. The means for signalling inform the practitioner of the proper position in the cortex by the emission of a signal with a low frequency and slow rhythm. In particular, beyond a certain value of impedance, corresponding to the impedance measured in the bone, the frequency as well as the rhythm of the signal remain relatively constant.

[0045] However, when the end of the instrument enters surrounding soft tissue, the practitioner is informed of this by an increase in the frequency and an acceleration in the rhythm of the signal.

[0046] Therefore, following this configuration, a small variation of the impedance in the bone is not heard while any variation in the impedance related to the penetration of the instrument in the surrounding soft tissue, as small as it may be, will be strongly heard.

[0047] In the same way, it is possible to create penetration instruments having other functionalities.

[0048] In particular, the drilling instrument (1) may advantageously comprise at lease one electrode (7) coinciding with the lateral surface of the drilling instrument (1), as well as two electrodes (5, 6) concentrically arranged at the distal end of the aforementioned drilling

instrument (1) (Fig. 7). It will thereby be possible, due to the configuration of the drilling instrument (1), to determine the presence and direction of a gap by means of electrodes (6, 7) as well as signal any perforation of the bone cortex by means of electrodes (5, 6). For this purpose, positioning a lateral electrode comprising a rod going to the distal end should be avoided. In fact, it is believed to be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

[0049] Advantageously, the electrodes may be arranged on the lateral surface of the drilling instrument to form annular bands of contact coinciding with the surface of the drilling instrument (1) (Fig. 4).

[0050] The electrodes may be advantageously arranged in the form of points of contact distributed in a homogenous manner on the surface of the drilling instrument (1). Such a distribution of the electrodes enables the volumetric detection of the perforations (Fig. 5). Such a configuration may thereby inform the surgeon of the lowest zone of impedance at all times.

[0051] Fig. 6 also illustrates implementation of a penetration instrument configured for tapping. Advantageously, the instrument (1) comprises a distal end in the form of a point and the lateral wall has cutting stops. One electrode (3) is arranged on at least one cutting stop. At least one other electrode (2) is also arranged at the distal end in point form of the instrument (1). Therefore, during the tapping operation, the surgeon is informed of the formation of a gap in real time not only at the end of the instrument and provoked by the distal end in point form on the instrument (1), but also laterally with respect to the wall of the instrument (1) and provoked by at least one of the cutting stops.

[0052] The invention is described above by way of example. It is understood that one skilled in the art is able to create different variants without departing from the framework of the devices as defined in the appended claims.

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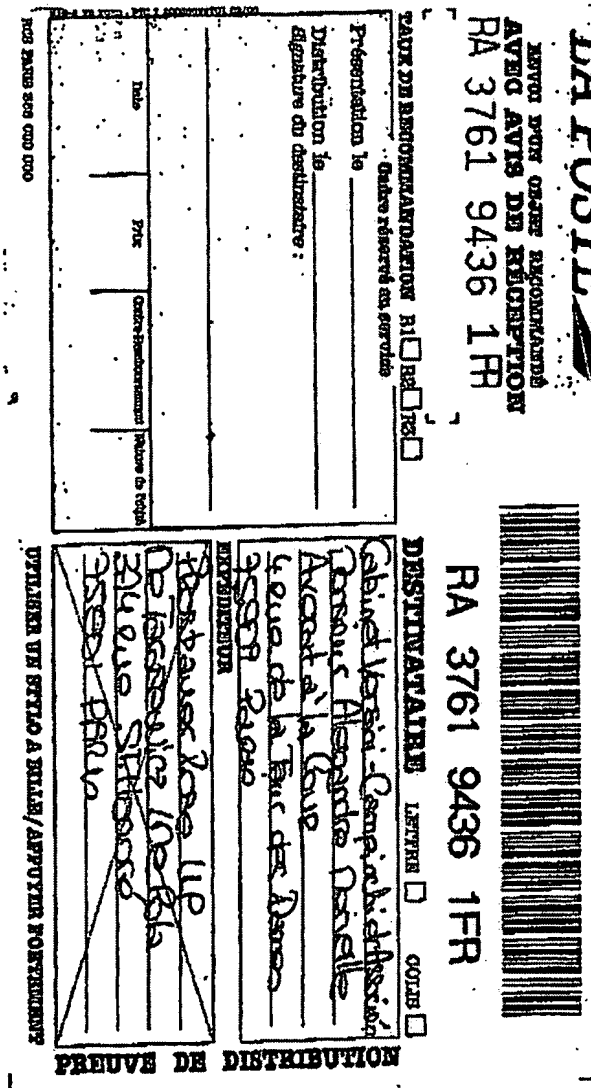

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19 septembre 2007

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Nos réf PASRV/757056.1
Dossier réf W1210/00158

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Villa Saint Antoine
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Lettre recommandée avec accusé de réception

DEPOT DE LA DEMANDE INTERNATIONALE PCT/FR2005/00340 AUX ETATS-UNIS

Monsieur,

Nous sommes les conseils de la société SpineVision SA.

Dans le cadre de l'enregistrement de la demande américaine n° 10/589,314 déposée le 11 août 2006 (35905/PCT/US) et correspondant à la demande internationale PCT/FR2005/00340 ayant pour titre "Device that monitor penetration of an instrument in an anatomic structure" concernant une invention pour laquelle vous êtes l'un des inventeurs désignés, notre cliente nous à demandé de vous transmettre les documents suivants :

- un exemplaire corrigé de "Combined Declaration, Power of Attorney and Petition",
- un exemplaire corrigé de "Assignment",
- un exemplaire du fascicule de publication de la demande PCT FR2005/00340,
- un exemplaire du texte de la demande telle que déposée aux Etats-Unis,
- un exemplaire du texte américain remanié.

Nous vous remercions d'en prendre connaissance et de nous retourner le document intitulé "Combined Declaration, Power of Attorney and Petition" ainsi que le document "Assignment" chacun signé de votre main.

Ces documents sont en effet indispensables à notre cliente dans le cadre de la délivrance du brevet américain correspondant à la demande internationale en cause.

Nous vous remercions de votre diligence et vous informons, conformément à nos règles déontologiques, que nous transmettons copie de la présente à votre conseil, notre Confrère Guillaume Teissonnière.

Nous vous prions de croire, Monsieur, en l'expression de notre considération distinguée.

Dominique Ménard
Avocat à la Cour

P.J.

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September, 19, 2007-10-03

dominique.menard@lovells.com

O/Ref. : PASRV/757056.1
Case ref. : W1210/00158

Mister Gérard Vanacker
Villa Saint Antoine
2 rue du Sautiquet
83380 Les Issambres

Registered letter with acknowledgement of receipt

FILING OF INTERNATIONAL APPLICATION PCT/FR2005/00340 IN THE USA

Dear Sir,

We are the legal advisers of company SpineVision SA.

In view of the registration of the US application No. 10/589,314 filed on August, 11, 2006 (35905/PCT/US) and corresponding to international application PCT/FR2005/00340 (Title : « Device that monitor penetration of an instrument in an anatomic structure »), relating to an invention for which you are one of the designated inventors, our client has asked us to transmit the following documents to you :

- a corrected copy of « Combined Declaration, Power of Attorney and Petition »,
- a corrected oopy of « Assignment »,
- a copy of the publication pamphlet of the application application PCT/FR2005/00340,
- a copy of the application text as filed in the USA,
- a copy of the US substitute text.

Kindly review these documents and send back to us the document « Combined Declaration, Power of Attorney and Petition » and the document « Assignment », both of them duly executed by yourself.

Indeed these documents are absolutely needed by our client in order to obtain the grant of the American patent corresponding to said international application.

We thank you in advance for your kind and prompt co-operation and inform you that, according to our ethical rules, we forward a copy of the present letter to your legal counsel, our colleague Guillaume Teissonnière.

Yours sincerely,

Signed
Dominique Ménard
Attorney at Law

Attorney Docket No. BDM-06-1214

☐ Original Application
☒ PCT National Application
U.S. Designated Office
☐ Continuation or Divisional Application
☐ Continuation-in-Part Application

COMBINED DECLARATION,
POWER OF ATTORNEY AND PETITION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE

☐ which is described in the specification and claims

☐ attached hereto.

☐ filed on _____

Application Serial No. _____

and was amended on _____
(*if applicable*)

☒ which is described in International Application No. PCT/FR2005/000340

filed February 11, 2005 and as amended on

_____(if any),

which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Attorney Docket No. BDM-06-1214

I hereby claim foreign priority benefits under Title 35, United States Code, §119(a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT International Application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application(s) for patent or inventor's certificate or of any PCT International Application having a filing date before that of the application on which priority is claimed:

Number	Country	Date of Filing (day,month,year)	Priority Claimed
0401362	France	11 February 2004	☒ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no
			☐ yes ☐ no

I hereby claim the benefit under Title 35, United States Code, §119(e) or §120 (as applicable) of any United States application(s) or §365(c) of any PCT International Application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International Application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112:

(Application Serial No.) *(Filing Date)* *(Status)(patented,pending,abandoned)*

(Application Serial No.) *(Filing Date)* *(Status)(patented,pending,abandoned)*

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered attorneys to prosecute this application and transact all business in the United States Patent and Trademark Office connected therewith:

T. Daniel Christenbury	Reg. No. 31,750	Steven A. Nash	Reg. No. 45,507
Paul A. Taufer	Reg. No. 35,703	Andrew A. Noble	Reg. No. 48,651
Thomas J. Durling	Reg. No. 31,349	Thomas R. Mancini	Reg. No. 50,157
Darius C. Gambino	Reg. No. 41,472	Richard L. Cruz	Reg. No. 52,783
William F. Lang	Reg. No. 41,928	William L. Bartow	Reg. No. 54,981
Paul Carango	Reg. No. 42,386		

SEND CORRESPONDENCE TO: **Customer No. 035811**, whose contact information is: IP Group of DLA Piper Rudnick Gray Cary US LLP One Liberty Place, Suite 4900 1650 Market Street Philadelphia, PA 19103	DIRECT TELEPHONE CALLS TO ATTORNEY OF RECORD AT: (215) 656-3300

COMBINED DECLARATION, POWER OF ATTORNEY AND PETITION
(Page 3)

Attorney Docket No. BDM-06-1214

I hereby petition for grant of a United States Letters Patent on this invention.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1. FULL NAME OF SOLE OR FIRST INVENTOR Maurice Bourlion	INVENTOR'S SIGNATURE	DATE
RESIDENCE Saint-Chamond, France	CITIZENSHIP France	
POST OFFICE ADDRESS 9 rue Jean Vincent, F-42400 Saint-Chamond, France		
2. FULL NAME OF JOINT INVENTOR, IF ANY Gerard Vanacker	INVENTOR'S SIGNATURE	DATE
RESIDENCE Les Issambres, France	CITIZENSHIP France	
POST OFFICE ADDRESS Villa Saint-Antoine, Rue du Sautiquet, F-83380 Les Issambres, France		
3. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY Dominique Petit	INVENTOR'S SIGNATURE	DATE
RESIDENCE Verton, France	CITIZENSHIP France	
POST OFFICE ADDRESS 2 rue des Peupliers, F-62180 Verton, France		
4. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
5. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
6. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		
7. FULL NAME OF ADDITIONAL JOINT INVENTOR, IF ANY	INVENTOR'S SIGNATURE	DATE
RESIDENCE	CITIZENSHIP	
POST OFFICE ADDRESS		

BDM-06-1214

ASSIGNMENT

WHEREAS, we, Maurice Bourlion, Gerard Vanacker and Dominique Petit, citizens of France, residing at 9 rue Jean Vincent, F-42400 Saint-Chamond, France; Villa Saint-Antoine, Rue du Sautiquet, F-83380 Les Issambres, France and 2 rue des Peupliers, F-62180 Verton, France, respectively, (hereinafter referred to as "the undersigned"), having made an invention entitled DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE for which on the date set forth below, unless otherwise indicated here, _____, the undersigned executed an application for United States Letters Patent,

WHEREAS, Spinevision. a corporation of France, with offices at 180 avenue Daumesnil, F-75012 Paris, France (hereinafter referred to as "assignee"), is desirous of acquiring the entire right, title and interest in said invention, said application and all letters patent issuing for said invention,

NOW, THEREFORE, in consideration of One Dollar ($1.00) and of other good and valuable consideration, receipt of which is hereby acknowledged, the undersigned, intending to be legally bound, does hereby sell, assign and transfer to the assignee the entire right, title and interest, for the United States of America, its territories and possessions, and for all foreign countries, in said invention, including said patent application, all divisions and continuations thereof, all rights to claim priority based thereon, all rights to file foreign applications on said invention, and all letters patent and reissues thereof, issuing for said invention in the United States of America and in any and all foreign countries.

It is agreed that the undersigned shall be legally bound, upon request of the assignee, or its successors or assigns or a legal representative thereof, to supply all information and evidence of which the undersigned has knowledge or possession, relating to the making and practice of said invention, to testify in any legal proceeding relating thereto, to execute all instruments proper to patent the invention in the United States of America and foreign countries in the name of the assignee, and to execute all instruments proper to carry out the intent of this instrument. If the undersigned includes more than one individual, these obligations shall apply to all of the undersigned both individually and collectively.

The rights and property herein conveyed by the undersigned are free and clear of any encumbrance.

EXECUTED on _____, 20__, at _____.

_____
Maurice Bourlion

_____
Gerard Vanacker

_____
Dominique Petit

_____
Witness

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété Intellectuelle
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(71) Déposant (*pour tous les États désignés sauf US*) : SPINEVISION [FR/FR]; 180, avenue Daumesnil, F-75012 Paris (FR).

(72) Inventeurs; et

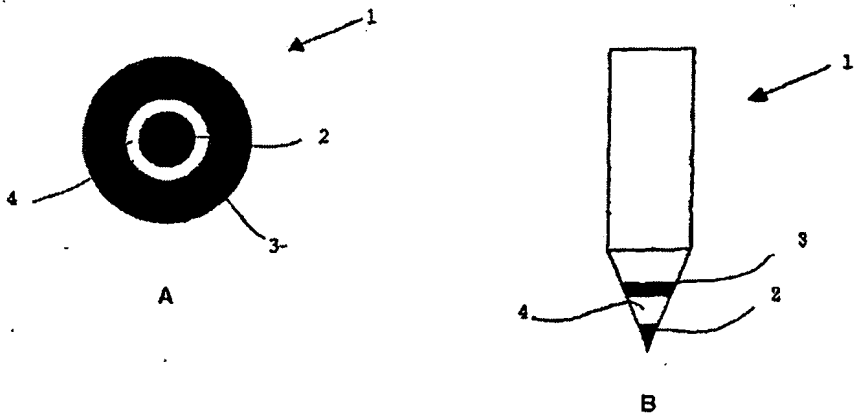
(75) Inventeurs/Déposants (*pour US seulement*) : BOURLION, Maurice [FR/FR]; 9, rue Jean Vincent, F-42400 Saint-Chamond (FR). VANACKER, Gérard [FR/FR]; 52, avenue François Adam, F-94100 Saint-Maur (FR). PETIT, Dominique [FR/FR]; 2, rue des Peupliers, F-62180 Verton (FR).

(74) Mandataire : SAYETTAT, Julien; Breesé Derambure Majerowicz, 38, avenue de l'Opéra, F-75002 Paris (FR).

[Suite sur la page suivante]

(54) Title: DEVICE FOR MONITORING THE PENETRATION OF AN INSTRUMENT INTO AN ANATOMICAL STRUCTURE

(54) Titre : DISPOSITIF POUR LE SUIVI DE LA PENETRATION D'UN INSTRUMENT DANS UNE STRUCTURE ANATOMIQUE



(57) Abstract: The invention relates to a device for monitoring the penetration of an instrument (1) into an anatomical structure, particularly a bone structure. The inventive device comprises a voltage source which powers at least two electrodes and a means for measuring the impedance between said electrodes. The invention is characterised in that the electrodes (2, 3) are located on the penetrating instrument (1) such as to present a flush constant contact surface that is dependent on how far the penetrating instrument (1) is inserted into the bone structure.

(57) Abrégé : La présente invention se rapporte à un dispositif pour le suivi de la pénétration d'un instrument (1) dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes et un moyen de mesure de l'impédance entre lesdites électrodes, caractérisé en ce que lesdites électrodes

[Suite sur la page suivante]

WO 2005/077283 A1

(81) **États désignés** *(sauf indication contraire, pour tout titre de protection nationale disponible)* : AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) **États désignés** *(sauf indication contraire, pour tout titre de protection régionale disponible)* : ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), européen (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Publiée :

— *avec rapport de recherche internationale*

— *avant l'expiration du délai prévu pour la modification des revendications, sera republiée si des modifications sont reçues*

En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

(2, 3) sont situées sur ledit instrument de pénétration (1) façon à présenter une surface de contact affleurante et constante en fonction du degré d'enfoncement dudit instrument de pénétration (1) dans ladite structure osseuse.

DISPOSITIF POUR LE SUIVI DE LA PÉNÉTRATION D'UN INSTRUMENT DANS UNE STRUCTURE ANATOMIQUE

La présente invention concerne le domaine de la chirurgie rachidienne, et plus particulièrement le suivi des instruments de pénétration au cours des opérations de perçage vertébral, cervical, thoracique, lombaire, sacré ou ilio sacré.

L'art antérieur connaît déjà des dispositifs permettant le suivi de la pénétration d'un instrument dans une structure anatomique, en particulier une structure osseuse.

On connaît le brevet européen EP0607688 décrivant une procédure et un système d'insertion d'une vis vertébrale pédiculaire, consistant à appliquer un potentiel électrique à la surface de la cavité, et à observer les réactions musculaires provoquées par cette stimulation.

On connaît également une solution consistant à mesurer la modification d'impédance dans la région voisine de la cavité osseuse explorée, à l'aide d'une sonde présentant une électrode venant en contact avec la paroi de la cavité osseuse, et une deuxième électrode placée sur le patient. Le but est de détecter des brèches dans la matière osseuse, par exemple lors d'une opération de préparation de la pose d'une vis pédiculaire dans une vertèbre.

L'information recueillie avec une telle solution est difficile à interpréter, car l'impédance mesurée entre les deux électrodes est perturbée par des artefacts liés à la variation d'enfoncement de la sonde dans la cavité. Les résistivités de l'air, des tissus musculaires, des tissus osseux et des brèches sont différentes, et le signal mesuré est une résultante de plusieurs paramètres masquant en partie l'information utile correspondant au passage de l'électrode de la sonde à proximité d'une brèche.

En outre, le dispositif proposé reste peu pratique du fait qu'il est nécessaire d'effectuer préalablement un calibrage (référence liée aux tissus mous).

Enfin, un tel dispositif reste de manipulation peu aisée du fait de la présence de câblages externes.

Le but de l'invention est de remédier à ces inconvénients en proposant un dispositif amélioré, dont le signal de sortie n'est pas perturbé par les variations dues à la profondeur d'engagement de l'instrument de pénétration.

La présente invention a également pour but de proposer un dispositif autonome, ne nécessitant aucun câblage externe.

La présente invention a également pour but de proposer un dispositif offrant des conditions de forage améliorées et sécurisées en avertissant l'opérateur de la formation de brèches.

À cet effet, l'invention concerne selon son acception la plus générale un dispositif pour le suivi de la pénétration d'un instrument dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes située sur ledit instrument et un moyen de mesure de l'impédance entre lesdites électrodes, et elle est remarquable en ce que lesdites électrodes sont situées sur ledit instrument de pénétration de façon à présenter une surface de contact affleurante et constante en fonction du degré d'enfoncement dudit instrument de pénétration dans ladite structure osseuse.

Plus précisément, la constance de la surface de contact des électrodes au cours de l'enfoncement dudit instrument de pénétration est obtenue de par les dimensions de ladite surface au regard des dimensions du trou formé dans la structure osseuse par ledit instrument de

pénétration, ladite surface de contact devant présenter des dimensions inférieures à celles du trou formé par ledit instrument de pénétration.

Par la notion de « surface de contact », il doit donc être compris le fait que la surface affleurante des électrodes présente des dimensions inférieures aux dimensions du trou formé par ledit instrument de pénétration.

De préférence, ledit dispositif comporte une électrode affleurant la surface distale dudit instrument de pénétration.

Par surface distale, on entend la surface de l'extrémité distale dudit instrument de pénétration.

Selon une première variante de l'invention, ledit dispositif comporte deux électrodes affleurant la surface distale dudit instrument de pénétration, lesdites électrodes étant disposées coaxialement et séparées l'une de l'autre par un isolant.

Selon une variante de réalisation de l'invention, ledit dispositif comporte deux électrodes affleurant la surface distale dudit instrument de pénétration, lesdites électrodes étant disposées l'une par rapport à l'autre symétriquement par rapport à l'axe longitudinal dudit instrument de pénétration.

Selon une autre variante de réalisation de l'invention, ledit dispositif comporte une pluralité d'électrodes affleurant la surface distale dudit instrument de pénétration.

Selon un mode de réalisation avantageux de l'invention, ledit dispositif comporte au moins une électrode présentant une surface de contact affleurant latéralement ledit instrument de pénétration.

Avantageusement, ladite électrode au moins présente une surface de contact annulaire.

Avantageusement, ledit dispositif comporte au moins deux électrodes présentant une surface de contact latérale annulaire.

Avantageusement, ledit dispositif comporte une électrode principale affleurant la surface distale dudit instrument de pénétration ainsi qu'une pluralité d'électrodes secondaires affleurant latéralement pour former des contacts annulaires espacés longitudinalement.

Selon un mode de réalisation préféré de l'invention, ledit dispositif comporte en outre des moyens de signalisation produisant un signal lors de la détection d'une variation de l'impédance par ledit moyen de mesure.

Avantageusement, le signal produit est un signal sonore dont la fréquence et/ou la cadence diminue(nt) en fonction de l'impédance mesurée. De préférence, la fréquence et/ou la cadence diminue(nt) non linéairement en fonction de l'impédance mesurée.

Ainsi, lorsque ledit instrument sort de la structure osseuse, le signal produit est un signal sonore aiguë à cadence rapide ; lorsque ledit instrument pénètre et reste dans la structure osseuse, le signal produit est un signal sonore grave à faible cadence.

Avantageusement, ledit dispositif comporte un canal central pour le passage d'un instrument additionnel.

L'invention sera mieux comprise à la lecture de la description qui suit, se référant aux figures annexées où :

- les figures 1A et 1B illustrent respectivement une vue en coupe frontale et une vue en coupe longitudinale d'un instrument de forage constituant un dispositif d'exploration de l'invention ;
- la figure 2 illustre une vue en coupe frontale d'une première variante de réalisation de l'instrument de forage ;

- la figure 3 illustre une représentation graphique du signal sonore émis par le dispositif d'exploration en fonction de l'impédance mesurée ;

- la figure 4 illustre une vue en coupe longitudinale d'une seconde variante de réalisation de l'instrument de forage ;

- la figure 5 illustre une vue en perspective d'une troisième variante de réalisation de l'instrument de forage ;

- la figure 6 illustre une vue en coupe longitudinale d'un instrument de pénétration constitué d'un taraud ; et

- la figure 7 illustre une vue en coupe longitudinale de l'instrument de pénétration selon une autre variation de l'instrument de forage.

Le dispositif selon l'invention est un dispositif permettant le suivi de la pénétration d'un instrument dans les structures osseuses d'un corps humain ou animal, lesdites structures présentant au moins deux zones d'impédance électrique différentes.

Lesdites électrodes, situées sur ledit instrument de pénétration (1), sont configurées pour présenter une surface de contact restant constante au cours de la pénétration dudit instrument de pénétration.

Lesdites électrodes sont reliées chacune à un générateur électrique délivrant une tension alternative, lequel comprend un circuit de mesure de l'impédance entre les deux électrodes (impédancemètre).

Ainsi, l'impédance des tissus pédiculaires étant strictement supérieure à celle des tissus musculaires, la détection d'une brèche se traduit par une diminution de l'impédance.

Ledit dispositif comporte en outre des moyens de signalisation produisant un signal spécifique lors de la

détection, par l'impédancemètre, d'une variation d'impédance, et donc de la pénétration de l'instrument dans une zone de tissus mous (moelle, nerfs), pour former ainsi une brèche dans le cortex osseux. Lesdits moyens de signalisation consistent en l'émission d'un signal visuel, tel qu'un témoin lumineux, d'un signal sonore, et/ou d'un signal tactile (vibreur, ...).

Un exemple préféré du principe de fonctionnement de la signalisation de la détection d'une brèche est décrit plus loin (figure 3).

Dans la partie ci-après, l'instrument de pénétration consiste en un instrument de forage (1). Cependant les configurations présentées ci-dessous sont bien entendu applicables aux autres instruments de pénétration (taraudage, curetage, spatulage, ...).

Les figures 1A et 1B illustrent une première configuration de l'instrument de forage (1) constituant ledit dispositif d'exploration selon l'invention.

Dans cette première configuration, l'instrument de forage (1) présente au niveau de son extrémité distale, deux électrodes (2, 3) de section circulaire et concentrique, l'électrode (2) intérieure étant séparée de l'électrode (3) extérieure par une couronne d'isolant (4).

L'électrode (2) constitue, dans cet exemple de réalisation, le pôle positif dudit dispositif électronique, l'électrode (3) le pôle négatif. Il est bien entendu évident qu'il ne s'agit ici que d'un exemple de réalisation, et que l'homme du métier pourra réaliser un dispositif électronique dont le pôle positif sera constitué par l'électrode (3) et le pôle négatif par l'électrode (2) sans pour autant sortir de l'invention.

Chaque électrode (2, 3) est disposée de sorte à affleurer la surface distale dudit instrument de forage (1).

Afin d'éviter toute perturbation du signal, la surface de l'électrode (3) affleurant la surface dudit instrument de forage (1) reste relativement petite par rapport aux dimensions du trou effectué dans le cortex osseux lors de l'opération de forage.

Lors de la pénétration de l'instrument (1) dans la structure osseuse, un signal est émis par lesdits moyens de signalisation lorsqu'une variation d'impédance mesurée entre lesdites électrodes (2, 3) est détectée par l'impédancemètre, indiquant la formation d'une brèche

A cet instant, le praticien est informé que l'extrémité de l'instrument de forage (1) vient de sortir du cortex osseux pour pénétrer dans une zone de tissus mous. Le praticien, s'il le souhaite, modifie alors la trajectoire de l'instrument de forage (1) de sorte à revenir dans le cortex osseux.

La figure 2 illustre une seconde configuration de l'instrument de forage (1) constituant ledit dispositif d'exploration.

Dans cette seconde configuration, l'instrument de pénétration (1) présente au niveau de son extrémité distale deux électrodes (2, 3) de section circulaire sensiblement identique. Lesdites électrodes (2, 3) sont avantageusement disposées symétriquement par rapport à l'axe longitudinal de l'instrument de forage (1).

La position desdites électrodes (2, 3) étant connue, leur disposition sur l'extrémité distale donne des indications sur la position des brèches. En effet, la brèche détectée sera située entre les deux électrodes (2, 3) pour lesquelles un signal est émis.

Le nombre et la forme des électrodes étant donné ici à titre d'exemple, il est entendu que ledit instrument (1) de pénétration peut présenter des électrodes en nombre

supérieur et de forme différente. Il est à noter que la détection volumétrique de brèches sera d'autant plus précise que le nombre d'électrodes réparties à l'extrémité dudit instrument (1) sera élevé.

La figure 3 illustre la représentation graphique de la fréquence et/ou cadence d'un signal sonore émis par lesdits moyens de signalisation en fonction de l'impédance mesurée entre les électrodes.

Selon un mode de réalisation préférentiel de l'invention, la courbe correspondant à la fréquence et/ou la cadence du signal émis en fonction de l'impédance est décroissante et non linéaire (cf. figure 3). Ainsi, lorsque l'instrument de pénétration est situé dans le cortex osseux, l'impédance mesurée entre les électrodes correspond à l'impédance de l'os, cette impédance restant relativement constante. Lesdits moyens de signalisation informent le praticien de la position correcte dans le cortex par l'émission d'un signal de fréquence grave et de cadence lente. En particulier, au-delà d'une certaine valeur de l'impédance, correspondant à l'impédance mesurée dans l'os, la fréquence ainsi que la cadence des signaux restent relativement constantes.

En revanche, lorsque l'extrémité de l'instrument pénètre dans un tissu environnant mou, le praticien en est averti par une augmentation de la fréquence et une accélération de la cadence du signal.

Ainsi, suivant cette configuration, une faible variation de l'impédance dans l'os ne s'entendra pas alors que, toute variation d'impédance liée à la pénétration de l'instrument dans un tissu environnant mou, aussi faible soit elle, s'entendra fortement.

De la même façon, il est possible de réaliser des instruments de pénétration présentant d'autres fonctionnalités.

En particulier, ledit instrument (1) de forage pourra avantageusement comporter au moins une électrode (7) affleurant la surface latérale dudit instrument (1) de forage, ainsi que deux électrodes (5, 6) disposées concentriquement à l'extrémité distale dudit instrument (1) de forage (figure 7). Il sera ainsi possible, de par la configuration dudit instrument (1) de forage de déterminer la présence et la direction d'une brèche au moyen des électrodes (6, 7), ainsi que de prévenir une éventuelle perforation du cortex osseux au moyen des électrodes (5, 6). A cet effet, il devra être évité de positionner une électrode latérale consistant en une tige allant jusqu'à l'extrémité distale. Il serait en effet impossible, avec une telle configuration, de savoir si la zone détectée par les électrodes est latérale ou distale.

Avantageusement, des électrodes pourront être disposées sur la surface latérale de l'instrument de forage pour former des bandes de contact annulaires affleurant la surface de l'instrument de forage (1) (figure 4).

Selon une variante de réalisation de l'invention, les électrodes seront avantageusement disposées sous la forme de points de contact répartis de façon homogène sur la surface de l'instrument de forage (1), une telle répartition des électrodes permettant une détection volumétrique des perforations (figure 5). Une telle configuration permet ainsi d'informer à chaque instant le chirurgien de la zone d'impédance la plus faible.

La figure 6 illustre également la réalisation d'un instrument de pénétration configuré pour le taraudage.

Avantageusement, ledit instrument (1) est constitué d'une extrémité distale en forme de pointe et présente sur sa paroi latérale des arêtes coupantes. Une électrode (3) est disposée sur au moins une arête coupante. Au moins une autre électrode (2) est également disposée à l'extrémité distale en forme de pointe dudit instrument (1). Ainsi, lors de l'opération de taraudage, le chirurgien est informé en temps réel de la formation d'une brèche non seulement en bout de l'instrument et provoquée par l'extrémité distale en forme de pointe de l'instrument (1), mais également latéralement par rapport à la paroi dudit instrument (1) et provoquée par au moins une des arêtes coupantes. .

L'invention est décrite dans ce qui précède à titre d'exemple. Il est entendu que l'homme du métier est à même de réaliser différentes variantes de l'invention sans pour autant sortir du cadre du brevet.

REVENDICATIONS

1. Dispositif pour le suivi de la pénétration d'un instrument (1) dans une structure anatomique, en particulier une structure osseuse, comportant une source de tension alimentant au moins deux électrodes et un moyen de mesure de l'impédance entre lesdites électrodes, caractérisé en ce que lesdites électrodes (2, 3) sont situées sur ledit instrument de pénétration (1) de façon à présenter une surface de contact affleurante et constante en fonction du degré d'enfoncement dudit instrument de pénétration (1) dans ladite structure osseuse.

2. Dispositif selon la revendication 1, caractérisé en ce qu'il comporte une électrode affleurant la surface distale dudit instrument de pénétration (1).

3. Dispositif selon la revendication 1 ou la revendication 2, caractérisé en ce qu'il comporte deux électrodes affleurant la surface distale dudit instrument de pénétration (1), lesdites électrodes étant disposées coaxialement et séparées l'une de l'autre par un isolant (4).

4. Dispositif selon la revendication 1 ou la revendication 2, caractérisé en ce qu'il comporte deux électrodes affleurant la surface distale dudit instrument de pénétration (1), lesdites électrodes étant symétriques par rapport à l'axe longitudinal dudit instrument de pénétration.

5. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce qu'il comporte une pluralité d'électrodes affleurant la surface distale dudit instrument de pénétration (1).

6. Dispositif selon la revendication 1, caractérisé en ce qu'il comporte au moins une électrode présentant une surface de contact affleurant latéralement ledit instrument de pénétration (1).

7. Dispositif selon la revendication précédente, caractérisé en ce que ladite électrode au moins présente une surface de contact annulaire.

8. Dispositif selon la revendication 6 ou la revendication 7, caractérisé en ce qu'il comporte au moins deux électrodes présentant une surface de contact latérale annulaire.

9. Dispositif selon la revendication 1, caractérisé en ce qu'il comporte une électrode principale affleurant la surface distale dudit instrument de pénétration (1) ainsi qu'une pluralité d'électrodes secondaires affleurant latéralement pour former des contacts annulaires espacés longitudinalement.

10. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce qu'il comporte en outre des moyens de signalisation produisant un signal lors de la détection par ledit moyen de mesure de l'impédance une variation de l'impédance.

11. Dispositif selon la revendication précédente, caractérisé en ce que le signal produit est un signal sonore dont la fréquence et/ou la cadence diminue(nt) en fonction de l'impédance mesurée.

12. Dispositif selon la revendication précédente, caractérisé en ce que la fréquence et/ou la cadence

diminue(nt) non linéairement en fonction de l'impédance mesurée.

13. Dispositif selon l'une quelconque des revendications 10 à 12, caractérisé en ce que le signal produit lorsque ledit instrument sort de la structure osseuse est un signal sonore aiguë à cadence rapide.

14. Dispositif selon l'une quelconque des revendications 10 à 12, caractérisé en ce que le signal produit lorsque ledit instrument pénètre la structure osseuse est un signal sonore grave à faible cadence.

15. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce que ledit dispositif est un dispositif autonome.

16. Dispositif selon l'une quelconque des revendications précédentes, caractérisé en ce qu'il comporte un canal central pour le passage d'un instrument additionnel.

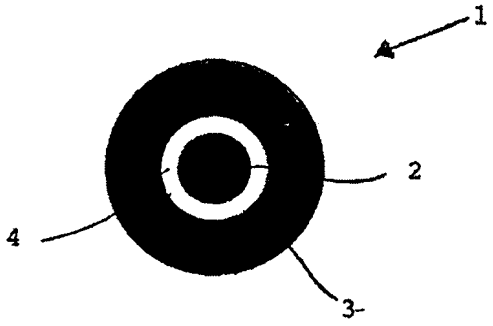


Fig. 1A

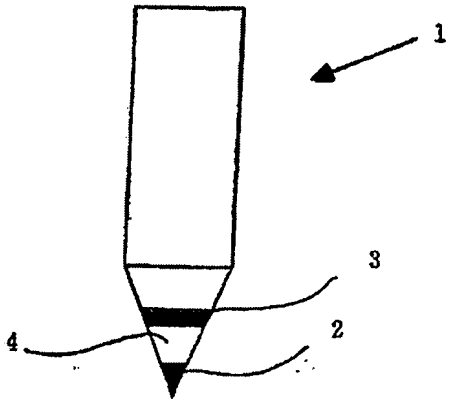


Fig. 1B

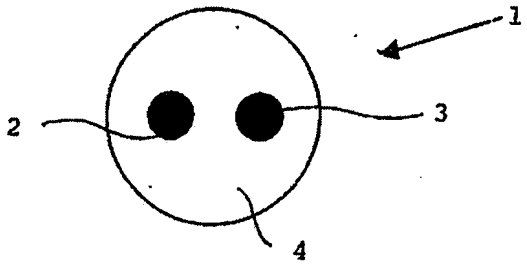


Fig. 2

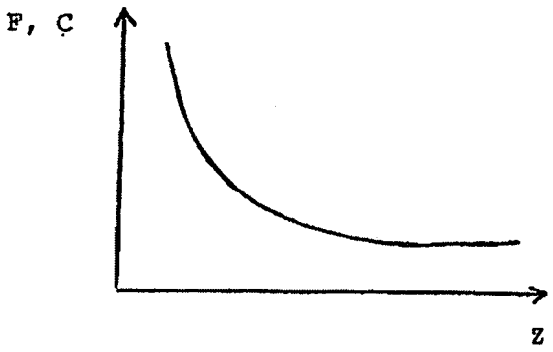


Fig. 3

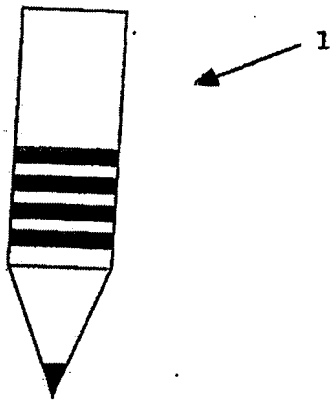


Fig. 4

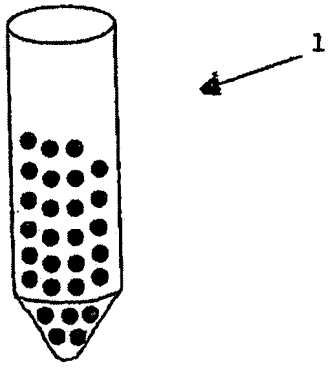


Fig. 5

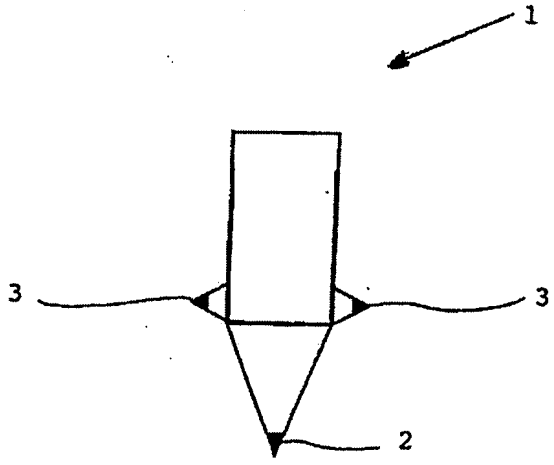


Fig. 6

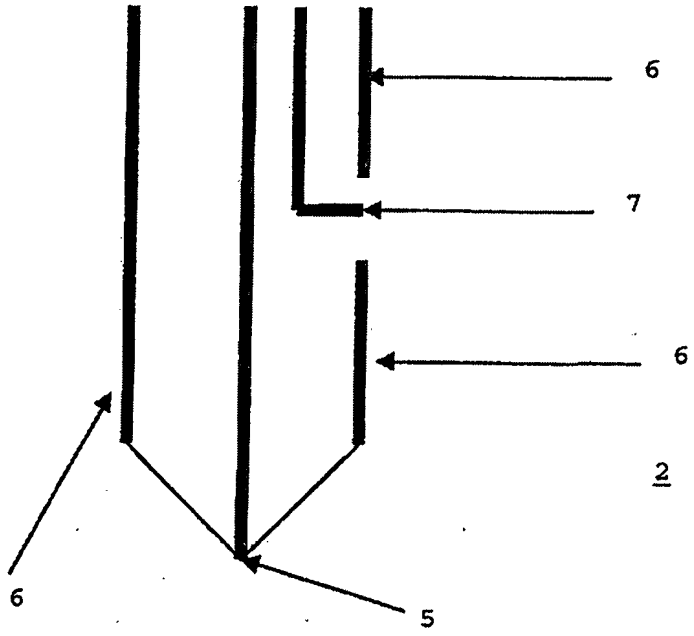


Fig. 7

INTERNATIONAL SEARCH REPORT

Int[redacted]al Application No
PCT/FR2005/000340

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61C A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/068076 A (SPINEVISION) 21 August 2003 (2003-08-21) page 8, line 17 - line 19 page 11, line 7 - line 12 page 11, line 34 - page 12, line 4 page 15, line 6 - line 10 page 17, line 26 - line 32 figures 1,4,7,13	1-16
A	US 6 391 005 B1 (LUM P.ET AL) 21 May 2002 (2002-05-21) column 1, line 62 - column 2, line 4 column 3, line 28 - line 49 column 6, line 46 - column 7, line 16 figures 1,2	
A	EP 0 607 688 A (NEUBARDT S.L.) 27 July 1994 (1994-07-27) cited in the application	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 June 2005	20/06/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nice, P

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ɔnal Application No
PCT/FR2005/000340

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 03068076	A	21-08-2003	FR	2835732 A1	15-08-2003
			AU	2003216974 A1	04-09-2003
			EP	1474046 A1	10-11-2004
			WO	03068076 A1	21-08-2003
US 6391005	B1	21-05-2002	DE	19914485 A1	18-11-1999
			GB	2335990 A	06-10-1999
			JP	11309124 A	09-11-1999
			US	2002042594 A1	11-04-2002
EP 0607688	A	27-07-1994	EP	0607688 A1	27-07-1994
			US	5474558 A	12-12-1995

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale No
PCT/FR2005/000340

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 7 A61B17/16

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 7 A61B A61C A61N

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
X	WO 03/068076 A (SPINEVISION) 21 août 2003 (2003-08-21) page 8, ligne 17 - ligne 19 page 11, ligne 7 - ligne 12 page 11, ligne 34 - page 12, ligne 4 page 15, ligne 6 - ligne 10 page 17, ligne 26 - ligne 32 figures 1,4,7,13	1-16
A	US 6 391 005 B1 (LUM P.ET AL) 21 mai 2002 (2002-05-21) colonne 1, ligne 62 - colonne 2, ligne 4 colonne 3, ligne 28 - ligne 49 colonne 6, ligne 46 - colonne 7, ligne 16 figures 1,2	
A	EP 0 607 688 A (NEUBARDT S.L.) 27 juillet 1994 (1994-07-27) cité dans la demande	

☐ Voir la suite du cadre C pour la fin de la liste des documents

☒ Les documents de familles de brevets sont indiqués en annexe

* Catégories spéciales de documents cités:

"A" document définissant l'état général de la technique, non considéré comme particulièrement pertinent

"E" document antérieur, mais publié à la date de dépôt international ou après cette date

"L" document pouvant jeter un doute sur une revendication de priorité ou cité pour déterminer la date de publication d'une autre citation ou pour une raison spéciale (telle qu'indiquée)

"O" document se référant à une divulgation orale, à un usage, à une exposition ou tous autres moyens

"P" document publié avant la date de dépôt international, mais postérieurement à la date de priorité revendiquée

"T" document ultérieur publié après la date de dépôt international ou la date de priorité et n'appartenenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention

"X" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive par rapport au document considéré isolément

"Y" document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier

"&" document qui fait partie de la même famille de brevets

Date à laquelle la recherche internationale a été effectivement achevée	Date d'expédition du présent rapport de recherche internationale
8 juin 2005	20/06/2005

Nom et adresse postale de l'administration chargée de la recherche internationale	Fonctionnaire autorisé
Office Européen des Brevets, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Nice, P

Formulaire PCT/ISA/210 (deuxième feuille) (Janvier 2004)

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale No
PCT/FR2005/000340

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)		Date de publication
WO 03068076	A	21-08-2003	FR	2835732 A1	15-08-2003
			AU	2003216974 A1	04-09-2003
			EP	1474046 A1	10-11-2004
			WO	03068076 A1	21-08-2003
US 6391005	B1	21-05-2002	DE	19914485 A1	18-11-1999
			GB	2335990 A	06-10-1999
			JP	11309124 A	09-11-1999
			US	2002042594 A1	11-04-2002
EP 0607688	A	27-07-1994	EP	0607688 A1	27-07-1994
			US	5474558 A	12-12-1995

EMC: EV 548524561 US

DEVICE TO MONITOR THE PENETRATION OF AN INSTRUMENT IN AN ANATOMIC STRUCTURE

[0001] The present invention concerns the domain of spinal surgery, and more particularly the monitoring of penetration instruments during operations of vertebral, cervical, thoracic, lumbar, sacral or ilio-sacral drilling.

[0002] The prior art is already familiar with devices used to follow the penetration of an instrument in an anatomic structure, in particular a bone structure.

[0003] We are aware of European patent EP0607688 describing a procedure and a system for the insertion of a pedicular vertebral screw, consisting of applying an electric potential to the surface of the cavity, and observing the muscular reactions provoked by this stimulation.

[0004] We are also aware of a solution consisting of measuring the modification in the impedance of the region neighbouring the explored bone cavity, using a sound presenting an electrode coming into contact with the wall of the bone cavity, and a second electrode placed on the patient. The purpose is to detect the gaps in bone matter, for example during an operation preparing for the insertion of a pedicular screw in a vertebra.

[0005] The information gathered with such a solution is difficult to interpret, since the impedance measured between the two electrodes is perturbed by artefacts related to the variation in the penetration of the sound in the cavity. The resistivities of the air, muscle tissue, bone tissue and gaps differ, and the signal measured is the result of several parameters that in part mask the useful information corresponding to the passage of the electrode of the sound near a gap.

[0006] In addition, the device proposed is not very practical since it first requires a calibration (reference related to soft tissue).

[0007] Finally, such a device remains not very easy to manipulate due to the presence of external cables.

[0008] The purpose of the invention is to correct these disadvantages by proposing an improved device, whose output signal is not disturbed by variations due to the depth of the entry of the penetration instrument.

[0009] The present invention also aims at proposing an autonomous device, not requiring external cabling.

[0010] The present invention also aims at proposing a device offering improved and safer drilling conditions by informing the operator of the formation of gaps.

[0011] For this purpose, according to its most general acceptation, the invention concerns a device to monitor the penetration of an instrument in an anatomic structure, in particular a bone structure, comprising a source of current supplying at least two electrodes located on the aforementioned instrument and a means to measure the impedance between the aforementioned electrodes, and it is remarkable in that the aforementioned electrodes are located on the aforementioned penetration instrument so as to present a coinciding and constant contact surface as a function of the degree of entry of the aforementioned penetration instrument in the aforementioned bone structure.

[0012] More precisely, the invariability of the contact surface of the electrodes during the entry of the aforementioned penetration instrument is obtained by the dimensions of the aforementioned surface with respect to the dimensions of the hole formed in the bone structure by the aforementioned penetration instrument, since the dimensions of the aforementioned contact surface should not exceed those of the hole formed by the aforementioned penetration instrument.

[0013] The term "contact surface" refers to the fact that the dimensions of the surface coinciding with the electrodes is smaller than those of the hole formed by the aforementioned penetration instrument.

[0014] Preferably, the aforementioned device comprises an electrode coinciding with the distal surface of the aforementioned penetration instrument.

[0015] Distal surface refers to the surface of the distal end of the aforementioned penetration instrument.

[0016] According to a first variant of the invention, the aforementioned device comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument, since the aforementioned electrodes are coaxially placed and separated by an insulation.

[0017] According to one variant of the invention, the aforementioned device comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument, since the aforementioned electrodes are symmetrically placed with respect to a longitudinal axis of the aforementioned penetration instrument.

[0018] According to another variant of the invention, the aforementioned device comprises a plurality of electrodes coinciding with the distal surface of the aforementioned penetration instrument.

[0019] According to an advantageous mode of implementation of the invention, the aforementioned device comprises at least one electrode presenting a contact surface laterally coinciding with the aforementioned penetration instrument.

[0020] Advantageously, the aforementioned electrode at least presents an annular contact surface.

[0021] Advantageously, the aforementioned device comprises at least two electrodes presenting an annular lateral contact surface.

[0022] Advantageously, the aforementioned device comprises a main electrode coinciding with the distal surface of the aforementioned penetration instrument as well as a plurality of secondary laterally coinciding electrodes to form longitudinally spaced annular contacts.

[0023] According to a preferred mode of implementation of the invention, the aforementioned device also comprises means of signalling producing a signal at the time of detection of a variation in the impedance by the aforementioned means of measurement.

[0024] Advantageously, the signal produced is a sound signal whose frequency and/or rhythm decreases as a function of the impedance measured. Preferably, the frequency and/or rhythm non linearly reduce as a function of the impedance measured.

[0025] Therefore, when the aforementioned instrument leaves the bone structure, an acute sound signal with a rapid rhythm is produced. When the aforementioned instrument penetrates and remains in the bone structure, a low-pitched sound signal with a low rhythm is produced.

[0026] Advantageously, the aforementioned device comprises a central channel for the passage of an additional instrument.

[0027] The invention will be better understood upon reading the following description, referring to the appended figures where:

- figures 1A and 1B respectively illustrate a front section view and a longitudinal section view of a drilling instrument forming the exploration device of the invention;
- figure 2 illustrates a front section view of a first variant of the drilling instrument;
- figure 3 illustrates a graphic representation of the sound signal given off by the exploration device as a function of the impedance measured;

- figure 4 illustrates a longitudinal section view of a second variant of the drilling instrument;
- figure 5 illustrates a perspective view of a third variant of the drilling instrument;
- figure 6 illustrates a longitudinal section view of a penetration instrument comprising a tap; and
- figure 7 illustrates a longitudinal section view of the penetration instrument according to another variation of the drilling instrument.

[0028] The device according to the invention is a device to monitor the penetration of an instrument in the bone structures of a human or animal body, the aforementioned structures presenting at least two different zones of electric impedance.

[0029] The aforementioned electrodes, located on the aforementioned penetration instrument (1), are configured to present a contact surface that remains constant during the penetration of the aforementioned penetration instrument.

[0030] The aforementioned electrodes are each connected to an electric generator delivering an alternative current, which comprises a circuit to measure the impedance between the two electrodes (impedometer).

[0031] Therefore, since the impedance of the pedicular tissue is strictly superior that of muscle tissue, the detection of a gap results in a reduction in the impedance.

[0032] The aforementioned device also comprises means of signalling producing a specific signal at the time of the detection, by impedometer, of a variation in impedance, and therefore the penetration of the instrument in a zone of soft tissue (marrow, nerves), to thereby form a gap in the bone cortex. The aforementioned means of signalling consist of the emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator, -).

[0033] A preferred example of the operating principle of the signalling of the detection of a gap is described below (figure 3).

[0034] In the following section, the penetration instrument consists of a drilling instrument (1). However, the configurations presented below are of course applicable to other penetration instruments (tapping, curettage, spatulage, -).

[0035] Figures 1A and 1B illustrate a first configuration of the drilling instrument (1) composing the aforementioned exploration device according to the invention.

[0036] In this first configuration, the drilling instrument (1) has, at the distal end, two electrodes (2, 3) of circular and concentric section, inner electrode (2) being separated from outer electrode (3) by an insulation ring (4).

[0037] Electrode (2) comprises, in this example of implementation, the positive pole of the aforementioned electronic device, electrode (3) the negative pole. It is of course obvious that this is only an example of implementation, and that the man skilled in the art may create an electronic device whose positive pole will consist of electrode (3) and negative pole of electrode (2) without going beyond the invention.

[0038] Each electrode (2, 3) is arranged so as to coincide with the distal surface of the aforementioned drilling instrument (1).

[0039] In order to avoid any perturbation in the signal, the surface of electrode (3) coinciding with the surface of the aforementioned drilling instrument (1) remains relatively small compared with the dimensions of the hole made in the bone cortex during the drilling operation.

[0040] During the penetration of the instrument (1) in the bone structure, a signal is given off by the aforementioned means of signalling when a variation in the impedance measured between

the aforementioned electrodes (2, 3) is detected by the impedometer, indicating the formation of a gap.

[0041] At that time, the practitioner is informed that the end of the drilling instrument (1) has just left the bone cortex to penetrate in a zone of soft tissue. The practitioner, if he so desires, then modifies the path of the drilling instrument (1) so as to return to the bone cortex.

[0042] Figure 2 illustrates a second configuration of the drilling instrument (1) comprising the aforementioned exploration device.

[0043] In this second configuration, the penetration instrument (1) presents two electrodes (2, 3) of sensibly identical circular section its the distal end. The aforementioned electrodes (2, 3) are advantageously symmetrically arranged with respect to the longitudinal axis of the drilling instrument (1).

[0044] Since the position of the aforementioned electrodes (2, 3) is known, their disposition on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes (2, 3) for which a signal is emitted.

[0045] Since the number and shape of the electrodes is here provided by way of example, it is understood that the aforementioned penetration instrument (1) may present a greater number of electrodes and their shape may differ. It should be noted that the volumetric detection of gaps will be more exact the higher the number of electrodes distributed at the end of the aforementioned instrument (1).

[0046] Figure 3 illustrates the graphic representation of the frequency and/or rhythm of a sound signal given off by the aforementioned means of signalling as a function of the impedance measured between the electrodes.

[0047] According to one preferential mode of implementation of the invention, the curve corresponding to the frequency and/or rhythm of the signal emitted as a function of the impedance is decreasing and not linear (see figure 3). Therefore, when the penetration instrument is located in the bone cortex, the impedance measured between the electrodes corresponds to the impedance of the bone, this impedance remains relatively constant. The aforementioned means of signalling inform the practitioner of the proper position in the cortex by the emission of a signal with a low frequency and slow rhythm. In particular, beyond a certain value of impedance, corresponding to the impedance measured in the bone, the frequency as well as the rhythm of the signal remain relatively constant.

[0048] However, when the end of the instrument enters surrounding soft tissue, the practitioner is informed of this by an increase in the frequency and an acceleration in the rhythm of the signal.

[0049] Therefore, following this configuration, a small variation of the impedance in the bone is not heard while any variation in the impedance related to the penetration of the instrument in the surrounding soft tissue, as small as it may be, will be strongly heard.

[0050] In the same way, it is possible to create penetration instruments presenting other functionalities.

[0051] In particular, the aforementioned drilling instrument (1) may advantageously comprise at lease one electrode (7) coinciding with the lateral surface of the aforementioned drilling instrument (1), as well as two electrodes (5, 6) concentrically arranged at the distal end of the aforementioned drilling instrument (1) (figure 7). It will thereby be possible, due to the configuration of the aforementioned drilling instrument (1) to determine the presence and direction of a gap by means of electrodes (6, 7) as well as signal any perforation of the bone

cortex by means of electrodes (5, 6). For this purpose, the positioning of a lateral electrode consisting of a rod going to the distal end should be avoided. In fact, it would be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

[0052] Advantageously, the electrodes may be arranged on the lateral surface of the drilling instrument in order to form annular bands of contact coinciding with the surface of the drilling instrument (1) (figure 4).

[0053] According to one variant of the invention, the electrodes will be advantageously arranged in the form of points of contact distributed in a homogenous manner on the surface of the drilling instrument (1). Such a distribution of the electrodes will enable the volumetric detection of the perforations (figure 5). Such a configuration may thereby inform the surgeon of the lowest zone of impedance at all times.

[0054] Figure 6 also illustrates the implementation of a penetration instrument configured for tapping. Advantageously, the aforementioned instrument (1) comprises a distal end in the form of a point and the lateral wall presents cutting stops. One electrode (3) is arranged on at least one cutting stop. At least one other electrode (2) is also arranged at the distal end in point form of the aforementioned instrument (1). Therefore, during the tapping operation, the surgeon is informed of the formation of a gap in real time not only at the end of the instrument and provoked by the distal end in point form on the instrument (1) but also laterally with respect to the wall of the aforementioned instrument (1) and provoked by at least one of the cutting stops.

[0055] The invention is described above by way of example. It is understood that the man skilled in the art is able to create different variants of the invention without going beyond the framework of the patent.

CLAIMS

1. Device to monitor the penetration of an instrument (1) in an anatomic structure, in particular a bone structure, comprising a source of current supplying at least two electrodes and a means to measure the impedance between the aforementioned electrodes, characterised in that the aforementioned electrodes (2, 3) are located on the aforementioned penetration instrument (1) so as to present a coinciding and constant contact surface as a function of the degree of penetration of the aforementioned penetration instrument (1) in the aforementioned bone structure.

2. Device according to claim 1, characterised in that it comprises an electron coinciding with the distal surface of the aforementioned penetration instrument.

3. Device according to claim 1 or claim 2, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being coaxially arranged and separated from each other by an insulation.

4. Device according to claim 1 or claim 2, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being symmetrical with respect to the longitudinal axis of the aforementioned penetration instrument.

5. Device according to any of the previous claims, characterised in that it comprises a plurality of electrodes coinciding with the distal surface of the aforementioned penetration instrument (1).

6. Device according to claim 1, characterised in that it comprises at least one electrode presenting a contact surface laterally coinciding with the aforementioned penetration instrument (1).

7. Device according to the previous claim, characterised in that the aforementioned electrode at least presents one annular contact surface.

8. Device according to claim 6 or claim 7, characterised in that it comprises at least two electrodes presenting a lateral annular contact surface.

9. Device according to claim 1, characterised in that it comprises one main electrode coinciding with the distal surface of the aforementioned penetration instrument (1) as well as a plurality of laterally coinciding secondary electrodes to form longitudinally spaced annular contacts.

10. Device according to any of the previous claims, characterised in that it also comprises means of signalling producing a signal during the detection by the aforementioned means to measure the impedance by a variation in impedance.

11. Device according to the previous claims, characterised in that the signal produced is a sound signal whose frequency and/or rhythm decrease as a function of the impedance measured.

12. Device according to the previous claim, characterised in that the frequency and/or rhythm decrease in a non linear manner as a function of the impedance measured.

13. Device according to any of claims 10 to 12, characterised in that the signal produced when the aforementioned instrument leaves the bone structure is an acute sound signal with a rapid rhythm.

14. Device according to any of claims 10 to 12, characterised in that the signal produced when the aforementioned instrument penetrates the bone structure is a low-pitched sound signal with a slow rhythm.

15. Device according to any of the previous claims, characterised in that the aforementioned device is an autonomous device.

16. Device according to any of the previous claims, characterised in that it comprises a central channel for the passage of an additional instrument.

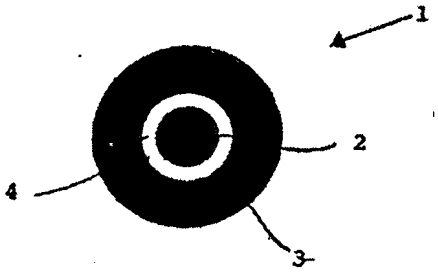


Fig. 1A

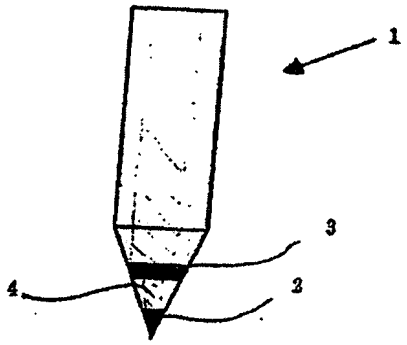


Fig. 1B

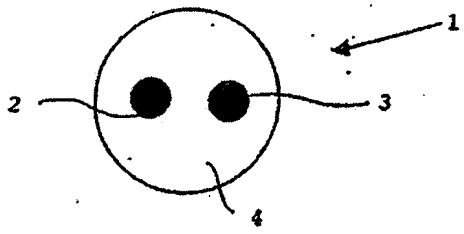


Fig. 2

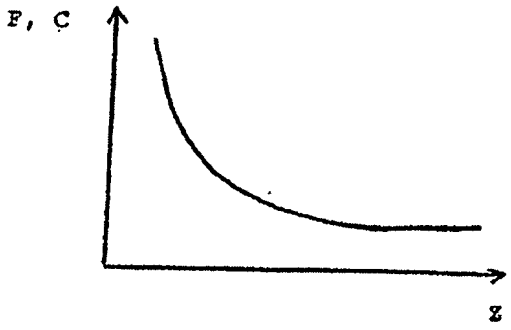


Fig. 3

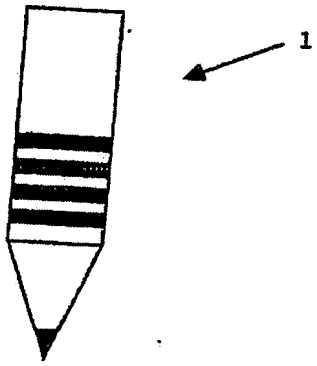


Fig. 4

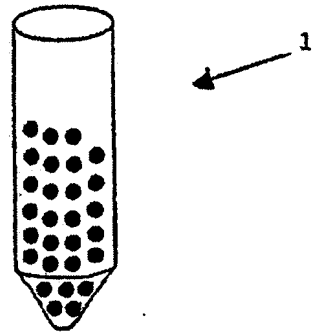


Fig. 5

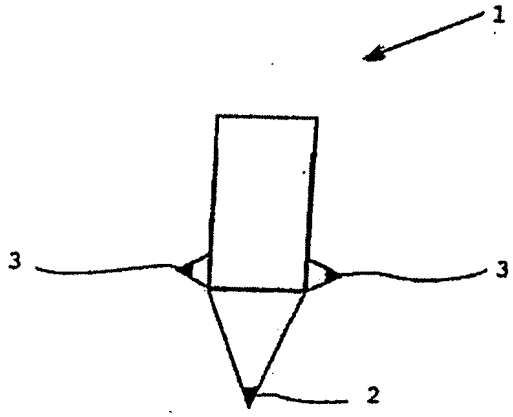


Fig. 6

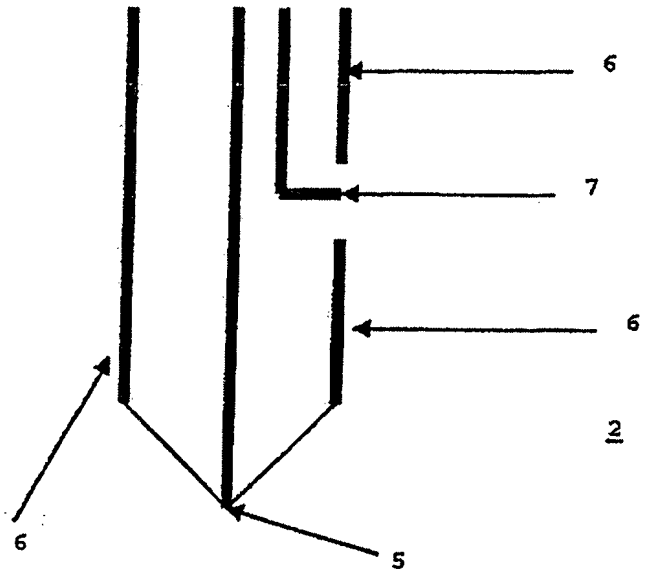


Fig. 7

CLAIMS

1. Device to monitor the penetration of an instrument (1) in an anatomic structure, in particular a bone structure, comprising a source of current supplying at least two electrodes and a means to measure the impedance between the aforementioned electrodes, the aforementioned electrodes (2, 3) are located on the aforementioned penetration instrument (1) characterised in that the device comprises at least a first electrode presenting a contact surface coinciding with the distal surface of the aforementioned penetration instrument and at least a second electrode presenting a contact surface coinciding with the lateral surface of the aforementioned penetration instrument (1), said contact surfaces dimension are so as to present a coinciding and constant contact surface as a function of the degree of penetration of the aforementioned penetration instrument (1) in the aforementioned bone structure.

2. Device according to claim 1, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being coaxially arranged and separated from each other by an insulation (4).

3. Device according to claim 1, characterised in that it comprises two electrodes coinciding with the distal surface of the aforementioned penetration instrument (1), the aforementioned electrodes being symmetrical with respect to the longitudinal axis of the aforementioned penetration instrument.

4. Device according to any of the previous claims, characterised in that the aforementioned electrode at least presents one annular contact surface.

5. Device according to claim 1, characterised in that it comprises one main electrode coinciding with the distal surface of the aforementioned penetration instrument (1) as well as a plurality of laterally coinciding secondary electrodes to form longitudinally spaced annular contacts.

6. Device according to claim 1, characterised in that it comprises a first electrode coinciding with the distal surface of the aforementioned penetration instrument (1), a second electrode coinciding with the lateral surface of the aforementioned penetration instrument (1) and a third electrode partially covering lateral surface of the aforementioned penetration instrument (1).

7. Device according to any of the previous claims, characterised in that it also comprises means of signalling producing a signal during the detection by the aforementioned means to measure the impedance by a variation in impedance.

8. Device according to the previous claim, characterised in that the signal produced is a sound signal whose frequency and/or rhythm decrease as a function of the impedance measured.

Replacement Sheet

9. Device according to the previous claim, characterised in that the frequency and/or rhythm decrease in a non linear manner as a function of the impedance measured.

10. Device according to any of claims 7 to 9, characterised in that the signal produced when the aforementioned instrument leaves the bone structure is an acute sound signal with a rapid rhythm.

11. Device according to any of claims 7 to 9, characterised in that the signal produced when the aforementioned instrument penetrates the bone structure is a low-pitched sound signal with a slow rhythm.

12. Device according to any of the previous claims, characterised in that the aforementioned device is an autonomous device.

13. Device according to any of the previous claims, characterised in that it comprises a central channel for the passage of an additional instrument.

Replacement Sheet

SUBSTITUTE SPECIFICATION (Clean Copy)

DEVICES THAT MONITOR PENETRATION OF AN INSTRUMENT IN AN ANATOMICAL STRUCTURE

Related Application

[0001] This is a §371 of International Application No. PCT/FR2005/000340, with an international filing date of February 11, 2005 (WO 2005/077283 A1, published August 25, 2005), which is based on French Patent Application No. 04/01362, filed February 11, 2004.

Technical Field

[0002] This disclosure relates to spinal surgery, more particularly, monitoring of penetration instruments during operations of vertebral, cervical, thoracic, lumbar, sacral or ilio-sacral drilling.

Background

[0003] Devices used to follow the penetration of an instrument in an anatomical structure, in particular, a bone structure are known.

[0004] Ep 0 607 688 describes a procedure and system for the insertion of a pedicular vertebral screw, incuding applying an electric potential to the surface of the cavity, and observing the muscular reactions provoked by this stimulation.

[0005] It is also known to measure the modification in the impedance of the region neighboring the explored bone cavity using a sound presenting an electrode coming into contact with the wall of the bone cavity, and a second electrode placed on the patient. The purpose is to

detect the gaps in bone matter, for example, during an operation preparing for the insertion of a pedicular screw in a vertebra.

[0006] The information gathered with such an approach is difficult to interpret since the impedance measured between the two electrodes is perturbed by artefacts related to the variation in the penetration of the sound in the cavity. The resistivities of the air, muscle tissue, bone tissue and gaps differ, and the signal measured is the result of several parameters that in part mask the useful information corresponding to the passage of the electrode of the sound near a gap.

[0007] In addition, the device is not very practical since it first requires calibration (reference related to soft tissue). Finally, such a device remains not very easy to manipulate due to the presence of external cables.

[0008] It could therefore be advantageous to provide a device whose output signal is not disturbed by variations due to the depth of the entry of the penetration instrument.

Summary

[0009] This invention relates to a device to monitor penetration of an instrument in an anatomical structure including at least two electrodes, a source of current supplying the at least two electrodes, and means for measuring impedance between the electrodes, wherein the electrodes are located on the penetration instrument, wherein the first electrode has a contact surface coinciding with a distal surface of the penetration instrument and the second electrode has a contact surface coinciding with a lateral surface of the penetration instrument, and wherein the contact surfaces are dimensioned to have a coinciding and constant contact surface as a function of a degree of penetration of the penetration instrument in the anatomical structure.

Brief Description of the Drawings

[0010] Selected, representative aspects of the devices will be better understood upon reading the following description, referring to the appended figures where:

Figs. 1A and 1B, respectively, are a front sectional view and a longitudinal sectional view of a drilling instrument forming an exploration device;

Fig. 2 is a front sectional view of a drilling instrument;

Fig. 3 is a graphic representation of the sound signal given off by the exploration device as a function of the impedance measured;

Fig. 4 is a longitudinal sectional view of a drilling instrument;

Fig. 5 is a perspective view of a drilling instrument;

Fig. 6 is a longitudinal sectional view of a penetration instrument comprising a tap; and

Fig. 7 is a longitudinal sectional view of a penetration instrument of a drilling instrument.

Detailed Description

[0011] We disclose devices to monitor penetration of an instrument in an anatomical structure, in particular, a bone structure, comprising a source of current supplying at least two electrodes located on the instrument and a means to measure the impedance between the electrodes. The electrodes are located on the penetration instrument to present a coinciding and constant contact surface as a function of the degree of entry of the penetration instrument in the bone structure.

[0012] More precisely, the invariability of the contact surface of the electrodes during entry of the penetration instrument is obtained by the dimensions of the surface with respect to the dimensions of the hole formed in the bone structure by the penetration instrument, since the

dimensions of the contact surface should not exceed those of the hole formed by the penetration instrument.

[0013] The term "contact surface" refers to the fact that the dimensions of the surface coinciding with the electrodes is smaller than those of the hole formed by the penetration instrument.

[0014] Preferably, the device comprises an electrode coinciding with the distal surface of the penetration instrument.

[0015] "Distal" surface refers to the surface of the distal end portion of the penetration instrument.

[0016] The device may comprise two electrodes coinciding with the distal surface of the penetration instrument, since the electrodes are substantially coaxially placed and separated by insulation.

[0017] The device may also comprise two electrodes coinciding with the distal surface of the penetration instrument since the electrodes are symmetrically placed with respect to a longitudinal axis of the penetration instrument.

[0018] The device may further comprise a plurality of electrodes coinciding with the distal surface of the penetration instrument.

[0019] The device may comprise at least one electrode having a contact surface laterally coinciding with the penetration instrument. Advantageously, the electrode at least has a substantially annular contact surface. Advantageously, the device comprises at least two electrodes having an annular lateral contact surface.

[0020] Advantageously, the device may comprise a main electrode coinciding with the distal surface of the penetration instrument as well as a plurality of secondary laterally coinciding electrodes to form longitudinally spaced annular contacts.

[0021] The device may also comprise means of signalling producing a signal at the time of detection of a variation in the impedance by the means of measurement.

[0022] Advantageously, the signal produced may be a sound signal whose frequency and/or rhythm decreases as a function of the impedance measured. Preferably, the frequency and/or rhythm non linearly reduce as a function of the impedance measured.

[0023] Therefore, when the instrument leaves the bone structure, an acute sound signal with a rapid rhythm is produced. When the instrument penetrates and remains in the bone structure, a low-pitched sound signal with a low rhythm is produced.

[0024] Advantageously, the device may comprise a central channel for the passage of an additional instrument.

[0025] The device monitors penetration of an instrument in the bone structures of a human or animal body, the structures having at least two different zones of electric impedance.

[0026] The electrodes, located on the penetration instrument (1), are configured to have a contact surface that remains constant during penetration of the penetration instrument.

[0027] The electrodes are each connected to an electric generator delivering an alternative current, which comprises a circuit to measure the impedance between the two electrodes (impedometer).

[0028] Therefore, since the impedance of the pedicular tissue is superior that of muscle tissue, the detection of a gap results in a reduction in the impedance.

[0029] The device also comprises means for signalling that produce a specific signal at the time of the detection, by impedometer, of a variation in impedance and, therefore, penetration of the instrument in a zone of soft tissue (marrow, nerves), to thereby form a gap in the bone cortex. The means for signalling include emission of a visual signal, such as a light, a sound signal, and/or a tactile signal (vibrator or the like).

[0030] A preferred example of the operating principle of the signalling of the detection of a gap is described below and shown in Fig. 3.

[0031] In the following section, the penetration instrument includes a drilling instrument (1). However, the configurations presented below are, of course, applicable to other penetration instruments (tapping, curettage, spatulage and the like).

[0032] Figs. 1A and 1B illustrate a first configuration of the drilling instrument (1) composing the exploration device.

[0033] In this first configuration, the drilling instrument (1) has, at the distal end portion, two electrodes (2, 3) of circular and concentric section, inner electrode (2) being separated from outer electrode (3) by an insulation ring (4).

[0034] Electrode (2) comprises in this example the positive pole of the electronic device, electrode (3) the negative pole. This is only one example of implementation and one skilled in the art may create an electronic device whose positive pole will include electrode (3) and negative pole of electrode (2) without going beyond the scope of this disclosure.

[0035] Each electrode (2, 3) is arranged to coincide with the distal surface of the drilling instrument (1).

[0036] In order to avoid any perturbation in the signal, the surface of electrode (3) coinciding with the surface of the drilling instrument (1) remains relatively small compared with the dimensions of the hole made in the bone cortex during the drilling operation.

[0037] During penetration of the instrument (1) in the bone structure, a signal is given off by the means effor signalling when a variation in the impedance measured between the electrodes (2, 3) is detected by the impedometer, indicating formation of a gap.

[0038] At that time, the practitioner is informed that the end of the drilling instrument (1) has just left the bone cortex to penetrate in a zone of soft tissue. The practitioner, if so desired, then modifies the path of the drilling instrument (1) to return to the bone cortex.

[0039] Fig. 2 illustrates a second configuration of the drilling instrument (1) comprising the exploration device.

[0040] In this second configuration, the penetration instrument (1) has two electrodes (2, 3) of sensibly identical circular section its the distal end. The electrodes (2, 3) are advantageously symmetrically arranged with respect to the longitudinal axis of the drilling instrument (1).

[0041] Since the position of the electrodes (2, 3) is known, their disposition on the distal end provides indications about the position of the gaps. In fact, the gap detected will be located between the two electrodes (2, 3) for which a signal is emitted.

[0042] Since the number and shape of the electrodes is here provided by way of example, it is understood that the penetration instrument (1) may have a greater number of electrodes and their shape may differ. It should be noted that the volumetric detection of gaps will be more exact the higher the number of electrodes distributed at the end of the instrument (1).

[0043] Fig. 3 illustrates the graphic representation of the frequency and/or rhythm of a sound signal given off by the means for signalling as a function of the impedance measured between the electrodes.

[0044] According to one preferential mode of implementation, the curve corresponding to the frequency and/or rhythm of the signal emitted as a function of the impedance is decreasing and not linear as shown in Fig. 3. Therefore, when the penetration instrument is located in the bone cortex, the impedance measured between the electrodes corresponds to the impedance of the bone, this impedance remains relatively constant. The means for signalling inform the practitioner of the proper position in the cortex by the emission of a signal with a low frequency and slow rhythm. In particular, beyond a certain value of impedance, corresponding to the impedance measured in the bone, the frequency as well as the rhythm of the signal remain relatively constant.

[0045] However, when the end of the instrument enters surrounding soft tissue, the practitioner is informed of this by an increase in the frequency and an acceleration in the rhythm of the signal.

[0046] Therefore, following this configuration, a small variation of the impedance in the bone is not heard while any variation in the impedance related to the penetration of the instrument in the surrounding soft tissue, as small as it may be, will be strongly heard.

[0047] In the same way, it is possible to create penetration instruments having other functionalities.

[0048] In particular, the drilling instrument (1) may advantageously comprise at lease one electrode (7) coinciding with the lateral surface of the drilling instrument (1), as well as two electrodes (5, 6) concentrically arranged at the distal end of the aforementioned drilling

instrument (1) (Fig. 7). It will thereby be possible, due to the configuration of the drilling instrument (1), to determine the presence and direction of a gap by means of electrodes (6, 7) as well as signal any perforation of the bone cortex by means of electrodes (5, 6). For this purpose, positioning a lateral electrode comprising a rod going to the distal end should be avoided. In fact, it is believed to be impossible, with such a configuration, to know whether the zone detected by the electrodes is lateral or distal.

[0049] Advantageously, the electrodes may be arranged on the lateral surface of the drilling instrument to form annular bands of contact coinciding with the surface of the drilling instrument (1) (Fig. 4).

[0050] The electrodes may be advantageously arranged in the form of points of contact distributed in a homogenous manner on the surface of the drilling instrument (1). Such a distribution of the electrodes enables the volumetric detection of the perforations (Fig. 5). Such a configuration may thereby inform the surgeon of the lowest zone of impedance at all times.

[0051] Fig. 6 also illustrates implementation of a penetration instrument configured for tapping. Advantageously, the instrument (1) comprises a distal end in the form of a point and the lateral wall has cutting stops. One electrode (3) is arranged on at least one cutting stop. At least one other electrode (2) is also arranged at the distal end in point form of the instrument (1). Therefore, during the tapping operation, the surgeon is informed of the formation of a gap in real time not only at the end of the instrument and provoked by the distal end in point form on the instrument (1), but also laterally with respect to the wall of the instrument (1) and provoked by at least one of the cutting stops.

[0052] The invention is described above by way of example. It is understood that one skilled in the art is able to create different variants without departing from the framework of the devices as defined in the appended claims.

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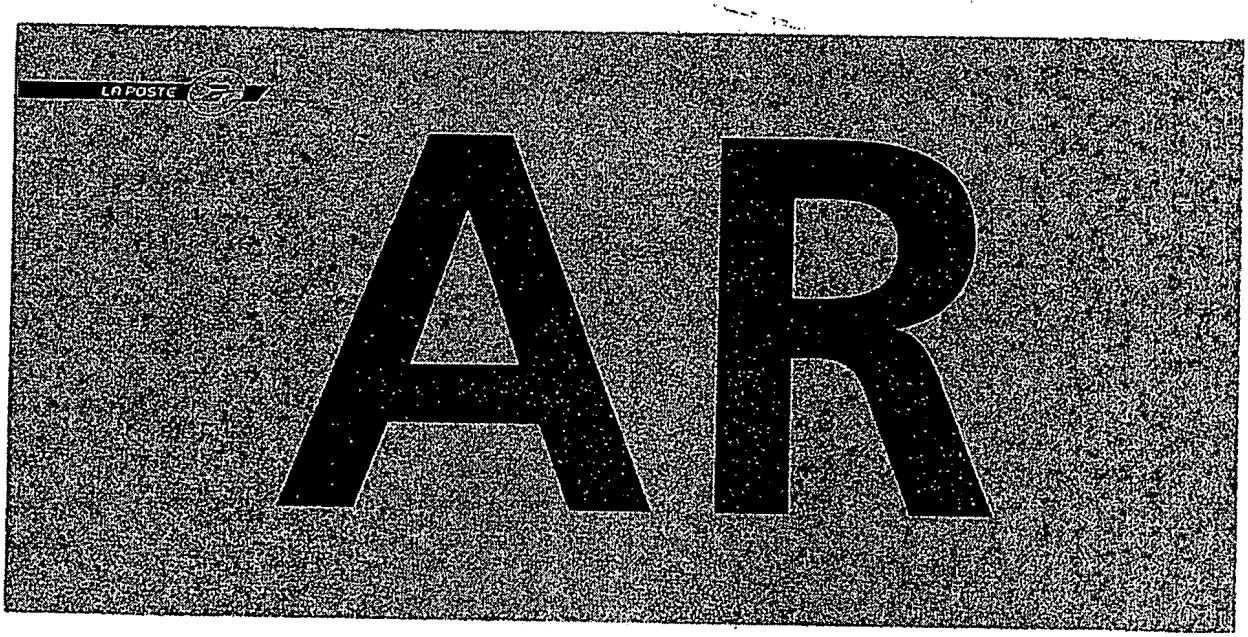
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